ORF-050, Issue 1.0, Date 4/04/14
Ref: SOP: 023/ORG

MEDICAL DEVICE PROTOCOL

INTRODUCTION

This protocol is written in support of Trust policy QS 24 Medical Devices and Equipment Management Policy. It is based upon "Managing Medical Devices, Guidance for Healthcare and Social Services Organisations April 2015 - produced by the Medicines and Healthcare products Regulatory Agency (MHRA).

Many of the principles of the management of medical devices are already covered by existing Welsh Blood Service (WBS) policies and procedures.

Please note all documents referenced in this policy are listed in Attachment 1.

DEFINITIONS

The full definition of medical devices and in vitro medical devices may be found in the medical device regulations. The definition is broad and will encompass many types of instruments, apparatus, and material for the diagnosis, monitoring, treatment or alleviation of disease i.e. things which have a "Medical Purpose".

Some examples of medical devices used by the WBS include:

- Dressings
- Syringes
- Equipment for measuring blood pressure
- Specimen receptacles
- Blood Agitators
- Defibrillators
- Certain types of software
- Diagnostic laboratory instruments
- Diagnostic laboratory reagents
- Diagnostic laboratory calibrator or control material

Medical device regulations do not include in its scope, medicines, blood or blood components which are covered by other regulations.

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POLICY/STATEMENT

The WBS shall ensure the safe and effective procurement, use and disposal of medical equipment, devices and diagnostic systems and that they:

a) Conform to health, safety and environmental legislation and guidance;

b) Are maintained, cleaned and calibrated in accordance with manufacturer's guidelines;

c) Are appropriate for their intended use and for the environment in which they are used;

d) Decontaminated as appropriate

e) Are supported by an ongoing programme of training and competence assessment for staff and users as appropriate; and

f) There is timely reporting and management of any device, equipment or system faults.

AIMS AND OBJECTIVES

The purpose of this document is to outline the lifecycle of medical devices, from acquisition to deployment to final disposal. It includes principles of medical device management and references to relevant WBS policies and procedures that may be applicable, depending upon the type or complexity of the device used.

LEGISLATION STANDARDS

Consumer protection, The Medical Devices Regulations 2002 transposed into law a number of EU directives including:

- 93/42/EEC Medical devices
- 98/79/EC In vitro diagnostic medical devices

Health and Care Standards April 2015 (Wales), Standard 2.9 Medical Devices, Equipment and Diagnostic Systems Health and Safety at Work etc Act 1974
The Management of Health and Safety Regulations 1999
The Provision and Use of Work Equipment Regulations 1998

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RESPONSIBILITIES

The overall responsibility of medical device management within Velindre NHS Trust lies with the Executive Director, Nursing, Quality and Service Improvement.

The Director of the WBS has overall responsibility for the application of this policy.

The Head of Quality Assurance and Regulatory Compliance:

- shall monitor that this policy is complied with
- shall update this policy as required
- will ensure any medical device incidents are reported to the MHRA as required (**MP-54**).

Heads of Departments must ensure that all applicable parts of this policy are applied to all medical devices in the areas to which they control and ensure that all appropriate records pertaining to medical devices are available for inspection.

The Compliance Manager will represent the WBS on the Trust's Medical Device Management group, and communicate relevant issue form the group to appropriate WBS managers

Staff:

- must participate in any training identified
- use medical devices only if competent to do so
- work to the Standard Operating Procedures (SOPs)/Manufacturer's instructions that are in place
- must report any adverse incidents, or device faults.

IMPLEMENTATION

Acquisition

Medical devices may be obtained by a number of different means. For medical devices that are purchased or leased, the WBS shall ensure that the devices are:

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- Acquired according to **POL(P)-028** (so far as the policy is applicable).
- Fit for intended purpose/application
- A full performance specification of the entire system is established before purchase
- Meet European Standards (EN) as applicable and are CE marked (unless part of a trial)
- Appropriate for the environment in which it is used
- Safe as reasonably practicable for the user
- Preferably user friendly, i.e. human factors are incorporated into the design
-
- Subject to Change Control (**MP-044**) and Validation Procedures, if critical to the process **(POL(P)-O35)**
- Used only for the purpose that they are intended for
- Purchased from critical suppliers (**MP-015**) if they are critical devices
- Cost effective over lifecycle (including any consumables required)

For devices that are obtained through loan, the WBS shall ensure that as well as the above they must:

- Be suitably decontaminated
- Have records that it has been maintained in a safe and reliable condition.

Note:

Trust Procurement must be informed if medical device has been obtained on loan, and will advise if a Loan Indemnity agreement is required.

For second hand devices, as well as the above, the WBS shall require:

- Records of any reconditioning work carried out, including a record of replacement parts

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- Copies of all maintenance and servicing that has been carried out, including the name of maintenance/servicing organisation
- Record of usage
- Fault log

Note:

For loaned devices, agreement should be made for who has the responsibility for maintenance.

Manufacture of devices and medical device software and modification/change of use of existing medical devices are outside the scope of this protocol.

Delivery/Installation

The WBS shall ensure, as a minimum, the following delivery checks:

- Checking that the correct product, complete with usage and maintenance information and any relevant accessories, has been supplied
- Ensuring that devices have been delivered in good condition, free from visible damage and defects and, where relevant, in good working order.
- Expiry dates are shown on packaging, as required, and are in-date
- The environment is suitable e.g. some types of medical devices may be subject to electromagnetic interference from mobile phones, others require appropriate storage conditions to prevent deterioration
- Where installation requires connection to electricity supplies, the WBS will ensure conformance to BS 7671

Note:

GMP critical medical devices shall be qualified as appropriate (**POL (P) -035; MP-050**), which includes calibration (**MP-017**), and adding to the system inventory (**SOP: 072/QAD**) where applicable

Equipment exceeding £5,000 in cost will be added to the capital asset register (**MP-033**).

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Note:

For many medical devices a risk assessment must be considered. The risk assessment may cover Quality (GMP) or Health & Safety or both (**POL(S)-014, MP-055**).

Instructions

The WBS shall ensure that all WBS staff that use medical devices, have available to them adequate health and safety information and, where appropriate, manufacturer's instructions or written instruction in the form of SOPs pertaining to the use of medical devices (**SOP: 023/ORG; POL(S)-007**).

SOPs shall take into consideration:

- Manufacturer's instructions
- All necessary information on storage, pre-use checks, use, maintenance and cleaning as required
- The conditions in which and the methods by which the medical device may be used
- Foreseeable abnormal situations and the action to be taken if such a situation were to occur
- Any conclusions to be drawn from experience in using the medical device
- Cleaning and/or decontamination as required

Training, Competency

WBS training procedures are described by **MP-019**. Before using a medical device, the WBS shall ensure that staff using the devices are:

- Appropriately trained in its operation in accordance with manufacturer's instructions and/or SOP's
- Able to recognise any defects or when the device is not working
- Aware of any maintenance, cleaning or decontamination that is required
- Aware of the meaning of any displays or alarms fitted

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- Aware of any calibration that needs to take place
- Aware of what action to take in the event of a fault, failure, or hazardous situation and have adequate Health and Safety information

The WBS shall develop and address appropriate competency management in the use of medical devices (for existing schemes see: **SOP: 001/CST; SOP: 017/LAB; SOP: 127/TTY**).

Maintenance, repair and calibration

WBS procedures on planned preventative equipment maintenance and unscheduled/emergency maintenance are described by **MP-046** (see also **SOP: 006/LAB**, **SOP: 019/ORG**).

WBS calibration procedures are described by **MP-017**. The WBS shall ensure that all work equipment including medical devices are maintained in an efficient state, in efficient working order, calibrated if required, and in good repair.

Inspection

User checks are described by **MP-046**.

If the safety of the equipment depends upon the installation conditions, then the WBS will inspect medical device equipment when it is first installed, and when it is moved or relocated. It shall be inspected to ensure that it has been correctly installed and operates safely. Also, where it is possible that conditions could cause deterioration in the equipment that result in dangerous conditions, it shall be regularly inspected to ensure that safety is maintained. This means that any damage must be picked up and put right in good time.

All inspections must be carried out by a competent person. Records of inspections shall be made and kept.

Service Contracts

Any contractual agreement with a maintenance and/or repair service provider should specify the level and type of service required by the WBS and should include, where appropriate:

- Reference to manufacturer's written instructions
- Availability, source and traceability of spare parts

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- Notification of any changes, including the use of alternative spare parts or methods
- Training and qualifications of staff (including GMP)
- Quality assurance systems (e.g. BS EN ISO 9001: 2015, ISO/IEC 17025:2005 or BS EN ISO 13485:2012)
- Requirement for adequate record keeping
- Use of sub-contractors
- Response times
- Loan equipment (where available)
- Disposal of obsolete equipment, parts and waste
- Required accreditation, e.g. United Kingdom Accreditation Service

Cleaning, Decontamination

The WBS has a number of cleaning and decontamination procedures which cover re-usable medical devices and other equipment: **SOP: 026/BCT; SOP: 114/BCP; SOP: 011/LAB**; **SOP: 090/TTY**.

The WBS shall ensure that medical devices are cleaned and decontaminated as appropriate. If written procedures are necessary, then they shall describe when cleaning and decontamination must take place and what records are required.

Prescription of Medical Devices

WBS do not prescribe medical devices.

Incidents

The WBS will ensure that all medical device incidents are recorded and investigated as appropriate, according to **MP-54**.

Medical Device alerts shall be handled according to **SOP: 023/QAD**.
Failures in medical devices, causing an incident likely to adversely affect patients in other NHS bodies, will be communicated to the MHRA.

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Replacement

The WBS shall review its medical device equipment periodically (**SOP: 023/VLN**) as appropriate, and will consider if the equipment requires replacement. Factors that will be considered will include:

- Whether the device is damaged or worn out beyond economic repair
- Its reliability based on service history
- Clinical or technical obsolescence
- Changes in local policies for device use
- Absence of manufacturer/supplier support
- Non-availability of correct replacement parts
- Non-availability of specialist repair knowledge
- Users' opinions
- Possible benefits of new model (features, usability, more clinically effective, lower running costs)
- If the device is re-called or the MHRA have issued a safety notice or alert

When the need to replace equipment is identified, then a business case and change control shall be prepared as appropriate.

Decommissioning

The WBS will ensure that any medical devices equipment deemed unfit for reuse will be decommissioned as appropriate. Decommissioning aims to make equipment safe and unusable, whilst minimising damage to the environment. Decommissioning should therefore include decontamination, making safe, and making unusable to ensure that an inappropriate person does not use the equipment and expose themselves to potential hazards. For GMP critical equipment, **SOP: 024/VLN** will be followed.

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Disposal

The WBS will ensure that medical devices that are no longer required will be disposed of appropriately, meeting appropriate environmental and other regulatory requirements. For devices that are capital assets, **MP-033** will be followed; for non-capital assets, **SOP: 004/GES**; for computer equipment, **SOP: 112/IT**S.

If a device stores identifiable patient information, this will be securely deleted when the device is taken out of service.

Records

The WBS shall keep records of medical devices, as appropriate, according to **MP-046**, and **MP-018**. These records should include (depending on the type of device):

- A unique identifier for the device, such as serial number
- Date of purchase
- Validation records
- Master configuration document
- Calibration records
- Cleaning records
- Decontamination certificates
- Where it was deployed
- Planned preventive maintenance
- Emergency maintenance and repairs
- The end-of-life date
- Training records
- Lot numbers
- Disposal records

Monitoring and Audit

The WBS will ensure that all policies and management procedures relating to the use of medical devices are audited according to **MP-003**. The WBS will carry out 2nd party audits for medical devices as deemed necessary. GMP critical equipment will be subject to periodic review (**SOP: 023/VLN**)

ATTACHMENTS

Attachment 1 Table of Policies and Procedures

Table of Policies and Procedures

Policies Pertinent to Medical Devices (this list is not exhaustive)	
POL(S)-007	Health and Safety Protocol
POL(S)-014	Quality Risk Management
POL(P)-028	Equipment Procurement Policy
POL(P)-035	Validation Policy
Management Procedures Pertinent to Medical Devices (this list is not exhaustive)	
MP-003	Audit
MP-007	Product Recall, Process Variation and Customer Concessions
MP-015	Critical Suppliers
MP-017	Control and Calibration of Measuring and Test Equipment
MP-018	Records Management
MP-019	Training of employees
MP-033	Capital Asset Register
MP-044	Change Control Process
MP-046	Maintenance of Equipment
MP-050	Approach to Validation
MP-054	Adverse Events, GMP Complaints and Incident Management
MP-055	Quality Risk Management (QRM)
SOPs Pertinent to Medical Devices (this list is not exhaustive)	
001/CST	Training And Assessment Of Clinical And Non Clinical Donor Facing Staff
023/QAD	Guidelines for Controlled Documentation
004/GES	Disposal of Equipment other than Capital assets
006/LAB	Machine Maintenance/Breakdown Procedures
019/ORG	Maintaining Critical Equipment
011/LAB	Decontamination of Equipment
017/LAB	Competency Assessment of Laboratory Staff
023/QAD	Procedure for Dealing with Medical Device Alerts/Hazard Notices
023/VLN	Guideline for Periodic Review Procedure
024/VLN	System Retirement Procedure
026/BCT	Care, Maintenance & Decontamination of Equipment and WBS Vehicles Whole Blood
090/TTY	General Cleaning and Decontamination Procedures
114/BCP	Maintenance and Calibration of Donation Clinic Equipment
127/TTY	WTAIL Strategy for Training and Competency Assessment
171/ITS	Decommissioning IT Equipment