ABM University Health Board	
Date of Meeting: 1st February 2018 **Name of Meeting: Quality and Safety Committee** **Agenda item: 7.2**	
Subject	*Ratification of the revised Medical Devices Management Policy*
Prepared by	Mike Rowlands – Head of MEMS
Approved by	Medical Devices Committee
Presented by	Hamish Laing, Executive Medical Director

1.0 Situation

The Policy on Medical Devices Management was endorsed by the Health Board's Medical Devices Committee on the 22nd November 2017 and is submitted to the Quality and Safety Committee with a request to be ratified. This policy has been screened for relevance to equality. No potential negative impact has been identified so a full equality impact assessment is not required.

2.0 Background

This previous policy had expired and was overdue for revision, a situation which the new policy addresses. The implementation of this policy addresses several concerns raised by a recent Internal Audit and will assist significantly in compliance with many of its recommendations (one of which was submission to this Committee for ratification).

3.0 Assessment

The policy outlines a systematic framework that will define the acquisition, deployment, training, maintenance (preventive maintenance and performance assurance), repair, decontamination, connectivity, decommissioning and disposal of medical devices. The policy will provide guidance in good equipment management and will promote practices that that will reduce the potential for harm and assist in the optimisation of cost, minimisation of risk and improved safety and performance of medical devices.

4.0 Recommendations

The Quality and Safety Committee is asked to;

Ratify the revised Medical Devices Management Policy.

Following ratification, the policy will be operationalised and appropriate training and education requirements organised.

MEDICAL DEVICES MANAGEMENT POLICY

Document Author:	**Mike Rowlands, Head of MEMS**
Approved by:	**Medical Devices Committee**
Approval date:	
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Document No	

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MEDICAL DEVICES AND EQUIPMENT MANAGEMENT POLICY

1. Policy Statement

1.1 Medical devices play a key role in healthcare and are vital for diagnosis, therapy, monitoring, rehabilitation and care. Effective management of this important resource is required to satisfy high quality patient care, clinical and financial governance as well as health and safety management including minimising risks of adverse events. Good management will greatly assist in reducing the potential for harm and assist in the optimisation of cost, minimisation of risk, improved safety and performance of medical devices.

1.2 This document will outline a systematic framework that will define the acquisition, deployment, training, maintenance (preventive maintenance and performance assurance), repair, decontamination, connectivity, decommissioning and disposal of medical devices.

2. Scope of Policy

2.1 This policy is supported by a range of other specific policies and directions for medical device management. It should be read and followed by all members of ABM University Health Board staff and contractors who are, or may become, involved in the selection, purchase, use, decontamination, maintenance, systems connectivity, transportation or disposal of a medical device.

3. Aims and Objectives

3.1 The purpose of this policy is to ensure that whenever a medical device is used it should be:

- Suitable for its intended purpose.
- Used in accordance with the manufacturer's instructions and established clinical practice, including connectivity with other systems.
- Used by competent trained staff.
- Be able to be cleaned and decontaminated using protocols and processes approved by the organisation and recommended by the manufacturer.
- Maintained in a safe and reliable condition.
- Disposed of appropriately at the end of its useful life, taking into consideration safety and information governance.

3.2 This policy and the associated documents aim to provide staff, carers and contractors with guidance on all aspects of medical devices. This covers the following areas:

- Management of medical devices
- Corporate and risk management structures
- Justification of need
- Selection and purchase (including standardisation)
- Technical specification
- Pre-use checks
- Training, information and instructions
- Decontamination, maintenance and servicing
- Devices prescribed or loaned out
- Medical device developments, trials & modifications
- Records and inventories, including traceability
- Regulatory compliance and related issues
- Adverse incident reporting and the dissemination of medical device field safety notices, patient safety notices: alerts etc
- Decommissioning and disposal

4. Responsibilities

4.1 ABM University Health Board operates and manages this policy through the Medical Devices Committee (MDC). The terms of reference of the MDC will be constructed to support the aims of this policy and will be updated on an annual basis. The MDC will report to either the Quality and Safety Committee or Health and Safety Committee, providing assurance to the organisation that robust process of medical device management is in place, and where not, ensure that the risks are identified and communicated through the organisations reporting channels.

4.2 The MDC's role should be to:

- Improve communication about medical devices within the organisation.
- Ensure involvement of clinicians, technical staff and users in relation to any proposed changes, including configuration settings relating to devices, where appropriate
- Define persons responsible for device management tasks, training and safe device operation, define and review the device management policy; review incidents including governance issues relating to medical device management.
- Reduce risk and improve patient's safety.
- Feed into the organisations reporting of Healthcare Standards, primarily HCS 2.9 – The management of medical equipment and diagnostic systems.
- Support internal and external audit

4.3 Membership of the MDC will be broad enough to ensure that the purpose of this policy is met and cascaded throughout the organisation. There needs to be appropriate representation from each of the following groups of staff:

- Service Delivery Units
- Clinical
- Biomedical Engineering
- Clinical trainers
- Informatics
- Management
- Infection control/decontamination
- Risk management
- Procurement
- Medical device trainers
- POCT
- Health and Safety
- Medical device users

In situations where medical equipment has specific associated hazards (e.g. ionising radiation, laser radiation, ultra-violet radiations, magnetic fields, radio frequencies etc.) the relevant adviser or specialist must be consulted on the acquisition of the equipment and the installation. A written risk assessment must be completed.

Where appropriate, the MDC should include links with specialist groups dealing with specialised medical devices (for example laboratories, radiation protection, radiology and renal dialysis).

Regular reports on medical device management are prepared for the MDC and, via MDC representation, to the Service Delivery Unit for inclusion in their risk register.

4.4 The Medical Director has overall responsibility for all aspects of medical device selection and usage.

4.5 The Service Delivery Units have responsibility for managing all aspects of control over medical devices used within their Unit. They may formally delegate responsibility for specific aspects of medical device management to a specialist department.

4.6 Departments providing specialist services such as Medical Physics and Clinical Engineering, Estates, Radiology and Pathology will appoint device co-ordinators to oversee the management of medical device services.

4.7 Ward/Departmental managers are responsible for the implementation of this policy and ensuring that adequate records are maintained.

4.8 All healthcare professionals are responsible for ensuring that medical devices are used safely and in line with relevant training and instructions, legislation and guidance, in particular where devices are used by patients or carers in the their treatment.

5. Definitions

5.1 For the purposes of the policy a medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- Investigation, replacement, modification, or support of the anatomy or of a physiological process,
- Supporting or sustaining life,
- Control of conception,
- Disinfection of medical devices
- Providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

6. Implementation/Policy Compliance

6.1 The implementation/ policy compliance will be defined in the Medical Equipment Management Directions document. This will define systems that will ensure that appropriate devices are available at the point of care, are understood by their user and can be used with confidence. These processes should be used in conjunction with this policy.

6.2 The Medical Equipment Management Directions will ensure that:

- Equipment is procured in line with organisational procedure as outlined in the Health Boards Standing Financial Instructions, Procurement Department guidelines and economic good practice.

- Capital equipment is recorded on the Health Board's Finance Department's asset register as well as on the MEMS central medical device database, which also records non-capital devices.
- Consideration is given to related /interconnected systems and their requirements.
- Equipment is suitable for (and only used for) its intended purpose and in accordance with British Standards or Manufacturers Specifications.
- Equipment is properly understood by users and all staff and patients must be appropriately trained and competent.
- Equipment is maintained in accordance with the manufacturer's guidance or managed via risk assessment.
- Risk is minimised, and where an incident (internal or external to the organisation) is identified, processes are in place to minimise the impact to patient care.
- Mechanisms are in place to distribute manufacturer's Field Safety Notices, MHRA Medical Device Alerts, other MHRA safety guidance to the appropriate people in the organisation.
- Mechanisms are in place to record and report adverse incidents relating to medical devices.
- Medical devices are cleaned and decontaminated in accordance with the Health Boards decontamination policy and/or manufactures guidance.
- There is connectivity between the healthcare organisation's strategic plan and the on the ground' equipment lifecycle management activities.
- Medical devices are decommissioned in accordance with the organisations decommissioning policy and/or manufacturers guidance, including data management and destruction.

7. Equality Impact Assessment Statement

An Equality Assessment screening tool has been completed and indicates that a full Equality Assessment is not required.

8. References

Medicines and healthcare products Regulatory Agency (MHRA)
Managing Medical Devices – Guidance for healthcare and social services organisations.
April 2015.

9. Getting Help

Help can be found from the following staff

- General Medical Device Issues – Head of MEMS
- Procurement – Head of Procurement, Shared Services
- Health and Safety – Head of Health and Safety
- Cleaning and decontamination - Head of Sterile Services and Decontamination.
- Consumable products procurement and incident reporting – Lead Nurse, Clinical procurement.
- Training – Head of Medical Device Training
- Point of Care - Point of Care Manager
- Radiation Protection – Consultant Clinical Scientist, Radiation Protection.
- IT security and governance – IT Governance Manager

10. Related Policies

The existing Health Board policies related to medical device management are:

- Health and Safety Policy
- Data Protection & Confidentiality Policy
- Equality Impact Assessment (EqIA) Tool & Guidance
- Health & Safety Policy
- ICT Procurement Policy
- Information Governance Strategy
- Information Security Policy
- Decommissioning Policy
- Mobile Communications
- Risk Management Policy
- Risk Management Strategy
- Safer Medical Sharps Policy
- Standing Orders - Schedule 06 Standing Financial Instructions
- Standing Orders - Schedule 11 Capital Projects Manual
- Incident Reporting

11. Information, Instruction and Training

Information on a wide range of medical device topics including**,** training, user manuals, etc can be found on the MEMS website; http://abmmems/

12. Main Relevant Legislation/Related Documents

- MHRA - Managing Medical Devices, Guidance for healthcare and social services organisations - April 2015
- Consumer Protection Act 1987 (Consumer Safety and Product Liability)
- Health and Safety at Work etc. Act (HASAWA) 1974
- Provision and Use of Work Equipment Regulations 1998 (PUWER)
- In Vitro Diagnostic Medical Devices Regulations
- Electricity at Work Regulations 1989
- Ionising Radiation (Medical Exposures) Regulations 2000
- Ionising Radiations Regulations 1999
- The Control of Artificial Optical Radiation at Work Regulations 2010
- Management of Health and Safety at Work Regulations 1999
- Sale and Supply of Goods Act 1994 (Chapter 35) [32]
- The Control of Substances Hazardous to Health Regulations 2002
- The Electrical Equipment (Safety) Regulations 1994
- The Electricity at Work Regulations 1989
- The Lifting Operations and Lifting Equipment Regulations 1998
- The Waste Electrical and Electronic Equipment Regulations 2006 and The Waste Electrical and Electronic Equipment (Amendment) Regulations 2007
- Health and Safety (Sharp Instruments in Healthcare) Regulations 2013)