GIG CYMRU NHS WALES | Iechyd Cyhoeddus Cymru Public Health Wales	**Name of Meeting** Quality, Safety and Improvement Committee **Date of Meeting** 13 December 2023 **Agenda item:** *5.2*

Section 1 - Policy / Procedure Information

Policy / Procedure Title	**Medical Devices and Equipment Management Policy**
Policy Lead	**Dr Eleri Davies**
Lead Executive	**Prof Meng Khaw**
PHW / All Wales?	**PHW**
Date of last Review	**01/02/2018**
Is the current policy / procedure within review date?	**No**
Approving Body /Group	**Quality, Safety and Improvement Committee**
Version Number	**Version 7**
Recommendation	
That the Quality, Safety and Improvement Committee: • Considers the information contained within the draft Medical Devices and Equipment Policy and Equalities Impact Assessment (Appendix) • **Note** that the Leadership Team have provided input into the Policy and Procedures • **Note** that the Leadership Team have approved the Procedure (included for information) and endorsed the Policy to the Committee • **Approve** the Medical Devices and Equipment Policy	

Section 3 – Details of the Review:	
Background:	
Reason for review	The policy review deadline had passed and the policy required review and updating to reflect changes in medical device regulations. Responsibility for the policy has transferred from QNAHPs and is now the responsibility of the Office of the Medical Director (OMD).
Description/Assessment	A review was undertaken in April 2023 of the policy's alignment to MHRA guidance. The change to Executive Director and author was made. Statements added about outsourcing, deployment, acquisition, modification and change of use and pre-UKCA/CE/CE UKNI marking. Links to Supporting Procedures updated and MHRA Guidance link added. Decontamination Policy renamed due to ongoing development and consultation. Changes approved at MDMG on 7 June 2023. Updated links to current policies. Removed link to contact "corporate governance" as broken. Use of Medical Equipment for Non-designated Purpose – text updated in line with MHRA guidelines Reference to decontamination updated in line with 'Decontamination of Medical Devices and Equipment Policy and Procedure'
Consultation	
Has this Policy / Procedure been through the appropriate 28 day consultation process?	Yes
Date range of consultation:	18 August 2023 – 19 September 2023
Please provide details of any feedback received and outline what changes if any were made to the document as a result:	Two comments received: 1. To highlight that in-vitro devices used in medical laboratories such as Microbiology and Screening services should be considered under this policy. 2. A request to add in detail on Software and Stand-alone apps that can be considered to be medical devices. In response both comments have been taken account of and additional information and links to MHRA documents added into the policy and procedure.
(Add detail)	

Had this policy / procedure been considered by any other groups?	Leadership Team- comments made (as below) in October 2023. Leadership Team the endorsed the policy and approved the procedure at its meeting on 2nd November 2023.
If so, please provide detail of any comments / feedback or amendments made to the documents as a result of this	Suggestions were made by the Leadership Team, and the Medical Devices Procedure has been updated to reflect the comments, as below: 8.1 the detail on the procurement team is incorrect so will need to be updated, This has been updated to reflect NWSSP contact information. 15.3 refers to a financial corporate governance policy, not sure what this is? should this section reference the disposal procedure? Reference to the suite of corporate governance and finance policies added in this section. Link to standing financial instructions also added as a linked policy on the cover page. The disposal procedure is listed on the cover page as a linked procedure, but I have also referenced it within this section as suggested. 19.2 references random audits carried out locally - should this include where these audits report to? Sentence added to clarify audits will be reported into the MDMG (which reports into QSIC)
Impact Assessments	
Equality and Health Impact Assessment	All Policies should be accompanied by an Equality and Health Impact Assessment. EHIA is attached.
Welsh Language Impact	The Policy / Procedure will be translated to welsh and available on the internet bilingually.
Risk and Assurance	It is a regulatory requirement to have a Medical Devices policy in place, regularly updated and

	taking account of MHRA updates. This update ensures compliance.
Health and Care Standards	This Policy / Procedure supports and/or takes into account the Health and Care Standards for NHS Wales Quality Themes
	Governance, Leadership and Accountability
	Theme 2 - Safe Care
	Theme 3 - Effective Care
Financial implications	There are no financial implications
People implications	There are no people implications
Socio Economic Duty	

5 - Implementation

Please complete the table below for this section, include any relevant actions required for implementation of this policy / procedure:

- How it will be implemented - If it requires resource, training or there are changes to current practice an implementation plan (template available on policy webpages) will be required to accompany the document giving clear timelines.
- If resources are required these should have been agreed prior to presentation to the Committee/Group.
- Info re any barriers to implementation and associated risk – explain how this will be mitigated.

Implementation plan (with timescales)		
Next steps	Timescale	Responsible officer(s)
Once ratified circulation to Divisional Leads with requirement for further dissemination to directorate / departmental leads for those areas that use medical devices.	October – December 2023	OMD
Implementation / training in relation to this policy to be monitored through Medicines Management Group	Ongoing	Exec Medical Director (Chair of MDMG)

6. Dissemination

The primary source for dissemination of the Medical Devices and Equipment Management Policy within the organisation, wider community and our partners will be via the internet site.

GIG CYMRU NHS WALES | Iechyd Cyhoeddus Cymru Public Health Wales	**Reference Number:** PHW 69 **Version Number:** 7 **Date of next review:** September 2024

Medical Devices and Equipment Management Policy

Policy Statement

It is the policy of Public Health Wales that all practicable steps should be taken to ensure all risks associated with the acquisition, management and use of medical devices are minimised to protect the public health and safeguard the interest of service users, carers and staff.

According to the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002), a medical device is described as any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which is intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process, or
- control of conception

This policy also applies to in vitro diagnostic (IVD) medical devices, such as the equipment, reagents and software that is utilised by the microbiology and screening laboratories which, in the main, do not come into direct contact with patients but may nevertheless cause indirect harm to patients if they do not perform as intended.

Public Health Wales must ensure that the medical devices and equipment meet appropriate standards of safety, quality, and performance, complying with all the relevant directives set out by the Medicines and Healthcare Products Regulatory Agency (MHRA) Managing Medical Devices Guidance and adherence to Gov.UK guidance for in vitro medical devices:

- In vitro diagnostic medical devices procurement safety quality and performance
- In vitro diagnostic point of care test devices

Software and Stand-alone apps can also be defined as Medical Devices under certain circumstances and the applicability of Medical Device Regulations must be considered when in-house software applications are developed or procured in

support of our services, (e.g. within Screening Services). Further guidance can be found at:
Medical devices: software applications (apps) - GOV.UK (www.gov.uk)
MHRA Software flowchart (publishing.service.gov.uk)

It is the responsibility of the organisation and all employees to contribute to the provision of safe and secure use of all medical devices for service users, carers and staff.
The aim is to ensure whenever a medical device is used, it should be:

(a) Suitable for its intended purpose;
(b) Properly understood by the user;
(c) Maintained in a safe and reliable condition;
(d) Stored and disposed of appropriately;
(e) Decontaminated in accordance with manufacturers guidance.

Policy Commitment

To provide a clear understanding of the organisation's principles regarding the management of medical devices and to set out standards and guidance to ensure systems are in place to provide assurances for the safe use and storage of equipment in Public Health Wales.

The aim of this policy is to support staff in understanding their responsibilities in relation to the management of medical devices. The knowledge and skills of staff, carers and services users have major implications for safety. Instructions must be clear, concise, and readily available. Training should be timely and effective and include procedures for the routine maintenance of medical devices by staff, carers, and service users.

The aim of the policy is to ensure that there are arrangements in place to ensure that medical device life cycles are appropriately governed and monitored. Where a medical device is outsourced, the lead for the use of the medical device must ensure that it complies with this policy. Medical device leads must ensure that equipment deployment, tracking and utilisation is monitored.

The policy aims to ensure that where a new medical device is acquired, relevant stakeholders are engaged in a discussion about their appropriateness and use.

Use of Medical Equipment for Non-designated Purpose; It should be noted that modification of equipment or use of any equipment for other than its intended purpose is a clear breach of the terms of the manufacturer's warranty. If a service user, carer or staff suffers harm in the process, the liability will not fall to the manufacturer.

Where a modification confers benefit, a fully documented risk assessment should be undertaken and risk management process defined before seeking approval from the MDMG.

Where a medical device is being deployed as part of a pre-UKCA-CE-CE UKNI marking clinical investigation, it must be approved by the Medical Devices Management Group.

This policy is based on statutory requirements produced by the Health and Safety Commission, Department of Health, Medicines and Healthcare Products Regulatory Agency and the Welsh Government including the:

- The Medical Devices Regulations 2002
- The Medical Devices (Amendment) Regulations 2008 and 2012
- The Medical Devices (Amendment) (EU Exit) Regulations 2021
- Health and Safety at Work etc. Act 1974
- Electricity at Work Regulations 1989
- Management of Health and Safety at Work Regulations 1999
- Provision and Use of Work Equipment Regulations 1998
- Health and Safety (Sharp Instruments in Healthcare) Regulations 2013

Supporting Procedures and Written Control Documents

Other related documents are:

- Medical Devices and Equipment Management Procedure
- Health and Safety Policy
- Incident Management Policy
- Radiation Safety Policy
- Risk Management Policy
- Waste Management Policy
- Infection Prevention Control Policy
- Decontamination of Medical Devices and Equipment Policy & Procedure
- Disposal of Obsolete and Surplus Equipment Procedure
- Alerts, Safety Notices and Other Guidance Policy

Scope

This policy applies to all medical devices used in Public Health Wales, associated establishments, or supplied to service users for use in their own homes irrespective of whether the equipment has been purchased, loaned, or received as a gift. The purpose of medical device management is to ensure that the right equipment is available when required, in a safe and serviceable condition and at a reasonable cost.

This policy applies to all staff (employed or contracted) who use, repair, or procure medical devices in the course of their work.

All staff are required to ensure that they work within the boundaries set out by this policy and are familiar with other associated guidance .

All staff are expected to understand and implement the decontamination requirements of each medical device in their service. The 'Decontamination of Medical Devices and Equipment Policy and Procedure', local departmental

Standard Operating Procedures and the Manufacturer's Instructions for Use should be referred to for detailed guidance on this.	
Equality and Health Impact Assessment	Integrated Screening Tool completed.
Approved by	Quality, Safety and Improvement Committee
Approval Date	
Review Date	
Date of Publication	
Group with authority to approve supporting procedures	Quality, Safety and Improvement Committee
Accountable Executive Director	Professor Fu-Meng Khaw, National Director Health Protection and Screening Services
Author	

Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author.

Summary of reviews/amendments				
Version number	**Date of Review**	**Date of Approval**	**Date published**	**Summary of Amendments**
1	01/04/15	01/10/09	01/10/09	First version of policy.
2	01/02/18	27/11/18	05/12/18	Review undertaken in February/March 2018. Changes made as a result of legislative changes. Documentation currently subject to internal approval processes.
3	07/06/23			Review undertaken in April 2023 of the policy's alignment to MHRA guidance. Change to Executive Director and author. Statements added about outsourcing, deployment, acquisition, modification and

				change of use and pre-UKCA/CE/CE UKNI marking. Links to Supporting Procedures updated and MHRA Guidance link added. Decontamination Policy renamed due to ongoing development and consultation. Changes approved at MDMG on 7 June 2023.
4	03/08/23			Updated links to current policies. Removed link to contact "corporate governance" as broken.
6	21/08/23			Use of Medical Equipment for Non-designated Purpose – text updated in line with MHRA guidelines. Reference to decontamination updated in line with 'Decontamination of Medical Devices and Equipment Policy and Procedure'.
7	20/09/23			Inclusion of references to in vitro devices and software following comments received during consultation period.

Template
Equality & Health Impact Assessment for

(Medical Devices Policy and Procedure)

Part 1

Please answer all questions:-

1.	For service change, provide the title of the Project Outline Document or Business Case and Reference Number	
2.	Name of Clinical Board / Corporate Directorate and title of lead member of staff, including contact details	Health Protection and Screening Services Fu-Meng Khaw, Executive Medical Director Meng.khaw@wales.nhs.uk
3.	Objectives of strategy/ policy/ plan/ procedure/ service	The Medical Devices Policy and Procedure is aimed at defining how medical devices are introduced, deployed and monitored in Public Health Wales in accordance with guidance from the regulator, the Medicines and Healthcare products Regulatory Agency (MHRA)
4.	Evidence and background information considered. For example • population data • staff and service users data, as applicable • needs assessment • engagement and involvement findings • research • good practice guidelines	The MHRA guidance on managing medical devices: Safeguarding public health (publishing.service.gov.uk)

	• participant knowledge • list of stakeholders and how stakeholders have engaged in the development stages • comments from those involved in the designing and development stages Population pyramids are available from Public Health Wales Observatory and the 'Shaping Our Future Wellbeing' Strategy provides an overview of health need.	
5.	Who will be affected by the strategy/ policy/ plan/ procedure/ service Consider staff as well as the population that the project/change may affect to different degrees.	All staff in Public Health Wales that use, manage or quality assure medical devices in the organisation. Medical devices are deployed in teams across the organisation. Beneficiaries of medical devices include patients, participants and members of staff.

Part 2- Equality and Welsh language

6. EQIA / How will the strategy, policy, plan, procedure and/or service impact on people?

Questions in this section relate to the impact on people on the basis of their 'protected characteristics'.

How will the strategy, policy, plan, procedure and/or service impact on:-	**Potential positive and/or negative impacts (unintended consequences) Opportunities or gaps**	**Action taken by Directorate.** Make reference to where the mitigation is included in the document, as appropriate **This column is to be updated in future reviews**	**Recommendations for improvement/ mitigation/ identified gaps or opportunities**
6.1 Age For most purposes, the main categories are: • under 18; • between 18 and 65; and • over 65	There is no identifiable impact.		
6.2 Persons with a disability as defined in the Equality Act 2010 Those with physical impairments, learning disability, sensory loss or impairment, mental health conditions, long-term	The deployment of some medical devices may be restricted in use for people with specific disabilities.	The deployment of medical devices will take into account persons with disabilities and adjustments made to ensure the device can be used safely either by	This will be built in to the training policy.

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts (unintended consequences) Opportunities or gaps	Action taken by Directorate. Make reference to where the mitigation is included in the document, as appropriate **This column is to be updated in future reviews**	Recommendations for improvement/ mitigation/ identified gaps or opportunities
medical conditions such as diabetes		taking adjustments and additional training.	
6.3 People of different genders: Consider men, women, people undergoing gender reassignment **NB** Gender-reassignment is anyone who proposes to, starts, is going through or who has completed a process to change his or her gender with or without going through any medical procedures. Sometimes referred to as Trans or Transgender	There is no identifiable impact.		
6.4 People who are married or who have a civil partner.	There is no identifiable impact.		

How will the strategy, policy, plan, procedure and/or service impact on:-	**Potential positive and/or negative impacts (unintended consequences) Opportunities or gaps**	**Action taken by Directorate.** Make reference to where the mitigation is included in the document, as appropriate **This column is to be updated in future reviews**	**Recommendations for improvement/ mitigation/ identified gaps or opportunities**
6.5 Women who are expecting a baby, who are on a break from work after having a baby, or who are breastfeeding.	Some medical devices may be harmful to pregnant women.	The deployment of medical devices is risk-assessed for use and users.	
6.6 People of a different race, nationality, colour, culture or ethnic origin including non-English speakers, gypsies/travellers, migrant workers	There is no identifiable impact.		
6.7 People with a religion or belief or with no religion or belief.	There is no identifiable impact.		

How will the strategy, policy, plan, procedure and/or service impact on:-	**Potential positive and/or negative impacts (unintended consequences) Opportunities or gaps**	**Action taken by Directorate.** Make reference to where the mitigation is included in the document, as appropriate **This column is to be updated in future reviews**	**Recommendations for improvement/ mitigation/ identified gaps or opportunities**
The term 'religion' includes a religious or philosophical belief			
6.8 People who are attracted to other people of: • the opposite sex (heterosexual); • the same sex (lesbian or gay); • both sexes (bisexual)	There is no identifiable impact.		
6.9 People according to their income related group: Consider people on low income, economically inactive, unemployed/workless, people who are unable to work due to ill-health	There is no identifiable impact.		
6.10 People according to where they live:	There is no identifiable impact.		

How will the strategy, policy, plan, procedure and/or service impact on:-	**Potential positive and/or negative impacts (unintended consequences) Opportunities or gaps**	**Action taken by Directorate.** Make reference to where the mitigation is included in the document, as appropriate **This column is to be updated in future reviews**	**Recommendations for improvement/ mitigation/ identified gaps or opportunities**
Consider people living in areas known to exhibit poor economic and/or health indicators, people unable to access services and facilities			
6.11 Consider any other groups and risk factors relevant to this strategy, policy, plan, procedure and/or service	There is no identifiable impact.		
6.12 Welsh Language			
There are 2 key considerations to be made during the development of a policy, project, programme, service to ensure there are no adverse effects and/or a positive or increased positive effect on: (please note these will continue to be reviewed to ensure Public Health Wales fulfils their duties to comply with one or more standards outlined within the Welsh Language Standards (No 7) Regulations 2018)			
Opportunities for persons to use the Welsh language	There is no identifiable impact.		
Treating the Welsh language no less	There is no identifiable impact.		

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts (unintended consequences) Opportunities or gaps	Action taken by Directorate. Make reference to where the mitigation is included in the document, as appropriate **This column is to be updated in future reviews**	Recommendations for improvement/ mitigation/ identified gaps or opportunities
favourably than the English language			

Part 3 – Health

Questions in this section relate to the impact on the health and wellbeing outcomes of the population **and** specific population groups who could be more impacted than others by a policy/project/proposal.

The part of the assessment identifies;

- which specific groups in the population could be impacted more (inequalities)
- what those potential impacts could be across the wider determinants of health framework?
- Potential gaps, opportunities to maximise positive H&WB outcomes
- Recommendations/mitigation to be considered by the decision makers

7. Identification of specific population groups

Use the WHIASU Population Groups checklist as a reference to identify the population groups who could be more impacted than others by a policy/project/proposal. The check list can be found on the PHW Integrated EqHIA guidance pages (requires link to PHW Intranet pages for additional information and resources)

The groups listed have been identified as more susceptible to poorer health and wellbeing outcomes (health inequalities) and therefore it is important to consider them in a HIA assessment. In a HIA, the groups identified, as

more sensitive to potential impacts will depend on the characteristics of the local population, the context, and the nature of the proposal itself.

7.1 Groups identified	Rational/explanation
None in addition to those in previous section.	

Assessment

Complete the wider determinants framework table below providing rational/evidence where appropriate:

1. Consider how the proposal could impact on the population and specific population groups identified above (positive/negative) for each of the wider determinants (the bullets under each determinant are there as a guide)
2. Record any unintended consequences (negative impacts) and/or gaps identified
3. Record any positive impacts or missed opportunities to maximise positive health and wellbeing outcomes
4. identify and record mitigation/recommendations where appropriate

Please note you may find that not all determinants are relevant to the project/plan however recording N/A is not acceptable a rational or evidence should be explained/referenced

Wider determinant for consideration	Positive impacts or additional opportunities	Unintended consequences or gaps	Population groups affected	Mitigation/recommendations
7.2 Lifestyles • Diet/nutrition/breastfeeding • Physical activity • Use of alcohol, cigarettes, e-cigarettes • Use of substances, non-prescribed drugs, abuse of prescription medication • Social media use • Sexual activity • Risk-taking activity i.e. gambling, addictive behaviour	There is no identifiable impact.			

7.3 Social and community influences on health • Adverse childhood experiences • Citizen power and influence • Community cohesion, identity, local pride • Community resilience • Domestic violence • Family relationships • Language, cultural and spirituality • Neighbourliness • Social exclusion i.e. homelessness • Parenting and infant attachment • Peer pressure • Racism • Sense of belonging • Social isolation/loneliness • Social capitol/support/networks • Third sector & volunteering	There is no identifiable impact.			
7.4 Mental Wellbeing • Does this proposal support sense of control? • Does it enable participation in community and economic life? • Does it impact on emotional wellbeing and resilience?	There is no identifiable impact.			
7.5 Living/ environmental conditions affecting health • Air quality • Attractiveness/access/availability/quality of area, green and blue space, natural space. • Health & safety, community, individual, public/private space • Housing, quality/tenure/indoor environment • Light/noise/odours, pollution • Quality & safety of play areas (formal/informal)	The use of medical devices may have an impact on carbon emissions.		Population-wide	Consideration under the NHS decarbonization strategy.

• Road safety • Urban/rural built & natural environment • Waste and recycling • Water quality				
7.6 Economic conditions affecting health • Unemployment • Income, poverty (incl. food and fuel) • Economic inactivity • Personal and household debt • Type of employment i.e. permanent/temp, full/part time • Workplace conditions i.e. environment culture, H&S	There is no identifiable impact.			
7.7 Access and quality of services • Careers advice • Education and training • Information technology, internet access, digital services • Leisure services • Medical and health services • Other caring services i.e. social care; Third Sector, youth services, child care • Public amenities i.e. village halls, libraries, community hub • Shops and commercial services Transport including parking, public transport, active travel	There is no identifiable impact.			
7.8 Macro-economic, environmental and sustainability factors • Biodiversity • Climate change/carbon reduction/flooding/heatwave • Cost of living i.e. food, rent, transport and house prices • Economic development including trade • Government policies i.e. Sustainable Development principle (integration;	The use of medical devices may have an impact on carbon emissions.		Population-wide	Consideration under the NHS decarbonization strategy.

collaboration; involvement; long term thinking; and prevention) • Gross Domestic Product • Regeneration				

Stage 3
Summary of key findings and actions Please answer question 8.1 following the completion of the EHIA and complete the action plan

Key findings: Impacts/gaps/opportunities	Actions (what is needed and who needs to do) to address the identified mitigation and recommendations	Lead		
The range of medical devices used in PHW is wide, ranging from Breast Imaging equipment to first aid kits. The medical devices policy and procedure ensures that the deployment of medical devices in PHW is safe, monitored and governed in accordance with the MHRA guidance. The equalities impact is considered to be minimal as medical devices are deployed equally across all population groups. There may be impact of users with	The risk assessment of medical devices should take into account disability and pregnancy.	Medical Devices Safety Officer and Local MDSOs		

certain characteristics, but these are risk-assessed on a case by case basis.				

Alternatively, if appropriate, please explain the steps taken to consult with and consider the differential impact of the changes on the various protected characteristic groups (part 2) or any specific identified population groups (part 3).

GIG CYMRU NHS WALES | Iechyd Cyhoeddus Cymru Public Health Wales	**Reference Number:** PHW 69/TP01 **Version Number:** 7 **Date of Next review:** November 2026

Medical Devices and Equipment Management Procedure

Introduction and Aims

Public Health Wales is committed to ensuring the health, safety and welfare of its staff and those who are affected by its activities. This procedure supports the **Medical Devices and Equipment Management Policy** and has been developed in line with the requirements of the *Health and Safety at Work Etc. Act 1974*.

Public Health Wales must ensure that the medical devices and equipment meet appropriate standards of safety, quality and performance, complying with all the relevant directives set out by the Medicines and Healthcare Products Regulatory Agency (MHRA).

The procedure aims to:

- To provide a clear understanding of Public Health Wales' principles regarding the management of medical devices and to set out standards and guidance to ensure systems are in place to provide assurances for the safe use and storage of equipment in the organisation.

Linked Policies, Procedures and Written Control Documents

- Public Health Wales Medical Devices and Equipment Management Policy (in review)
- Health and Safety Policy
- Incident Management Policy
- Radiation Safety Policy
- Risk Management Policy
- Waste Management Policy
- Infection Prevention Control Policy
- Decontamination of Medical Devices and Equipment Policy (in review)
- Disposal of Obsolete and Surplus Equipment Policy
- Standing Financial Instructions
- Alerts, Safety Notices and Other Guidance Policy

Scope

This procedure applies to all medical devices used in Public Health Wales, associated establishments or supplied to service users for use in their own homes irrespective of whether the equipment has been purchased, loaned or received

as a gift. The purpose of medical device management is to ensure that the right equipment is available when required, in a safe and serviceable condition and at a reasonable cost.

This procedure applies to all staff employed (or contracted) by Public Health Wales who use, repair or procure medical devices in the course of their work.

All staff are required to ensure that they work within the boundaries set out by this procedure.

All staff are expected to understand and implement the decontamination requirements of each medical device in their service. The 'Decontamination of Medical Devices and Equipment Policy and Procedure', local departmental Standard Operating Procedures, and Manufacturer's Instructions for Use should be referred to for detailed guidance on this.

Equality and Health Impact Assessment	EHIA Completed for the Medical Devices and Equipment Management Policy
Approved by	Leadership Team
Approval Date	02 November 2023
Review Date	02 November 2026
Date of Publication:	
Accountable Executive Director	Professor Fu-Meng Khaw, National Medical Director Health Protection and Screening Services
Author	

Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author.

Summary of reviews/amendments				
Version number	**Date of Review**	**Date of Approval**	**Date published**	**Summary of Amendments**
1	01.02.18	27.11.18	05.12.18	First version of procedure. Developed as a result of a review in February/March 2018.
2				Reviewed in April 2023 against MHRA guidelines.
3	03/08/23			Updated links to current policies. Removed link to contact "corporate governance" as broken. Expansion of Section 14 and addition of Appendix 2.
4	09/08/23			Use of Medical Equipment for Non-designated Purpose – section updated in line with MHRA guidelines
5	21/08/23			Reference to decontamination updated in line with 'Decontamination of Medical Devices and Equipment Policy and Procedure'.
6	20/09/23			Inclusion of references to in vitro devices and software within "Definitions section" following comments received during consultation period.
7	26/10/23			Updated as per feedback from LT 10/10/23.

Contents

1 Introduction

The aim of this procedure is to support staff in understanding their responsibilities in relation to the management of medical devices, in support of the Medical Devices and Equipment Management Policy.

2 Resource Implications

The resource implications of this procedure are primarily related to procurement and contractual costs associated with maintenance, replacement, disposal, servicing and repair of medical devices.

Failure to meet regulatory standards could lead to imposition of financial penalties, patient harm and reputational damage.

3 Definitions

The term *medical device c*overs a wide range of products used every day in primary and secondary healthcare settings.

According to the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002), a medical device is described as any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which is intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process, or
- control of conception

Within Public Health Wales, there are many pieces of equipment that fall within the definition of a medical device:

It should be noted that the definition of a medical device includes in vitro diagnostic (IVD) medical devices, such as the equipment, reagents and software utilised by the microbiology and screening laboratories which, in the main, do not come into direct contact with patients but may nevertheless cause indirect harm to patients if they do not perform as intended.

Public Health Wales must ensure that the medical devices and equipment meet appropriate standards of safety, quality, and performance, complying with all the relevant directives set out by the Medicines and Healthcare Products Regulatory Agency (MHRA) Managing Medical Devices Guidance and adherence to Gov.UK guidance for in vitro medical devices:

- In vitro diagnostic medical devices procurement safety quality and performance
- In vitro diagnostic point of care test devices

Software and Stand-alone apps can also be defined as Medical Devices under certain circumstances and the applicability of Medical Device Regulations must be considered when in-house software applications are developed or procured in support of our services, (e.g. within Screening Services). Further guidance can be found at:
Medical devices: software applications (apps) - GOV.UK (www.gov.uk)
MHRA Software flowchart (publishing.service.gov.uk)

Usage of Medical Devices is commonplace across Public Health Wales and training in their use should be part of an employee's induction in order for them to carry out their role. Public Health Wales expects all staff to adhere to the following principles before using ANY medical device:

- Always visually check the piece of equipment for cleanliness and signs of damage and correct settings before each use
- Ensure equipment has been serviced where appropriate by checking service label
- If the equipment requires disposables, ensure they are correct for the device and for its current settings
- All disposables are within expiry date and any associated packaging is intact before opening
- Do not use the piece of equipment unless you have been trained to do so
- Do not be afraid to ask for advice
- Ensure that all equipment is thoroughly decontaminated in line with cleaning schedules and manufacture instructions before and after use. This information should be logged locally
- Used within an appropriate environment

Manufacturer's Instructions must be readily available for each piece of equipment and it is essential that they are followed. Any deviation from the instructions may not only invalidate any warranty but could also cause an injury to the employee or service user.

4 Legislation and Best Practice Guidance

4.1 Statutory Requirements

The policy and associated procedure is based on statutory requirements produced by the Health and Safety Commission, Department of Health, Medicines and Healthcare Products Regulatory Agency and the Welsh Government including the:

- The Medical Devices Regulations 2002
- The Medical Devices (Amendment) Regulations 2008 and 2012
- The Medical Devices (Amendment) (EU Exit) Regulations 2021
- Health and Safety at Work etc Act 1974
- Electricity at Work Regulations 1989
- Management of Health and Safety at Work Regulations 1999
- Provision and Use of Work Equipment Regulations 1998
- Health and Safety (Sharp Instruments in Healthcare) Regulations 2013

4.2 Best Practice Guidance

- MHRA, 2021. Managing Medical Devices – Guidance for healthcare and social services organisations.
- MHRA Medical Devices: Guidance for manufacturers on vigilance
- MHRA Safeguarding Public Health Device Bulletin DB2011(01) Reporting Adverse Incidents and Disseminating Medical Device Alerts March 2011
- MHRA, 2008. Devices in Practice - a guide for professionals in health and social care
- NHS Wales Governance e-Manual: Medical Devices
- Device Bulletin Single-use Medical Devices: Implications and Consequences of Reuse Single use medical devices-implication reuse
- NHS Wales Shared Services Partnership - Specialist Estates Services publications

4.3 Mandatory Requirements

Department of Health Medicines and Healthcare Products Regulatory Agency
Decontamination of medical devices: a development plan for healthcare organisations
https://www.gov.wales/sites/default/files/publications/2019-07/decontamination-of-medical-devices-a-development-plan-for-healthcare-organisations.pdf

More details on decontamination guidance for PHW staff can be found in the Decontamination of Medical Devices and Equipment Policy and Procedure, local department Standard Operating Procedures, and the Manufacturer's Instructions for Use.

5 Acquiring Equipment – Safety Quality and Performance

Appropriate acquisition and selection of devices should be undertaken in accordance with section 3 of the MHRA's Managing Medical Devices Guidance for healthcare and social services organisations April 2014. In addition, reference should be made to the MHRA's publication Devices in Practice – a guide for professionals in health and social care, which includes a series of checklists that can help in the purchase, use and maintenance of medical devices and training.

6 Roles and Responsibilities

6.1 Chief Executive

The Chief Executive has the overall accountability for the management of medical devices.

6.2 Executive Director

The National Medical Director for Health Protection and Screening Services is the Board's nominated Director responsible for ensuring compliance with the policy and procedure.

This includes overall responsibility for ensuring compliance with all current regulations and approved guidance and best practice, and the implementation of the policy and procedure by:

- Communicating the policy and procedure to everyone who works at Public Health Wales
- Ensuring the policy and procedure is implemented by everyone who works in Public Health Wales

Delegating the performance of some of the duties related to medical equipment to Directors, Directorate Managers under his/her control.

6.3 Head of Estates and Health and Safety

The Head of Estates and Health and Safety and/or respective Health and Safety Manager for the Service for which the respective medical device is used are Public Health Wales' nominated Medical Devices Liaison Persons. They are responsible for ensuring the effective reporting of adverse incidents involving medical devices to the

Medicines and Healthcare Regulatory Agency (MHRA), the Health and Safety Executive (HSE) and the Surgical Material Testing Laboratory (SMTL), if appropriate, and the dissemination of advice and recommendations issued by them, including medical device alert notices throughout the organisation. When reporting adverse incidents involving medical devices and equipment the organisation's Incident Reporting Policy should be followed.

6.4 Medical Devices Management Group

The purpose of the Medical Devices Management Group (MDMG)is to ensure that medical device compliance in Public Health Wales complies with relevant regulation, legislation and guidance.

The MDMG is responsible for ensuring key issues such as, but not limited to, identifying, reviewing and managing adverse events, alerts and risks, providing and seeking expert advice and leadership on untoward incidents and oversee the ongoing use of medical device registers.

New medical devices for use within Public Health Wales NHS Trust services must be approved by the MDMG.

6.5 Health and Safety Group

The Health and Safety Group consists of wide-ranging representation from each Directorate/ division who will be responsible for co-ordinating the Directorate/ division's responses/actions and communications in respect of medical devices and equipment.

6.6 Divisional Level Responsibilities

Divisional Service Directors should ensure equipment management structures are in place and that systems are developed to ensure all staff are aware and take ownership of their responsibilities concerning the management of equipment in accordance with national guidelines including MDA DB9801 and Health and Care Standards, Standard 2 Safe Care, 2.9 Medical Devices, Equipment and Diagnostic Systems.

6.7 Departmental Managers should:

Identify individuals for specific tasks and responsibilities
Set objectives, standards and timescales and monitor performance in relation to equipment management in their areas of work.

Report problems/areas of concern to senior managers

Implement the policy/procedure for equipment management and monitor compliance with the Medical Devices and Equipment Management policy/procedure in their area.

Take part in the business planning process relating to equipment
Check competence of all staff upon induction and monitor/review competence of all staff as part of appraisal and risk management processes.

Identify training and support for department leads. Ensure all training and competence is documented.

Ensure adequate resources are provided for use of Personal Protective Equipment and decontamination methods.

6.8 Professional users should:

Work only within sphere of professional/personal competence.
Use equipment in a safe authorised manner, only for its intended or designated purpose, following manufacturers guidelines and local policies.

Work to all organisational policies and procedures relating to the procurement, use and disposal of equipment.
Report any adverse incidents and concerns relating to the use of equipment to line manager.

Equipment must not be used or maintained without appropriate training and staff have a responsibility to identify and report any training needs to their line manager.

Ensure decontamination processes are in accordance to manufacturers guidance.

7 Acquiring Equipment – Safety Quality and Performance

7.1 Acquisition

Appropriate acquisition and selection of devices should be undertaken in accordance with section 3 of the MHRA's *Managing Medical Devices Guidance for healthcare and social services organisations April 2014*. In addition, reference should be made to the MHRA's publication *Devices in Practice – a guide for professionals in health and social care*, which includes a series of checklists that can help in the purchase, use and maintenance of medical devices and training.

8 Procurement

8.1 Process

Public Health Wales has a responsibility to ensure they follow a compliant and robust procurement process. Advice and support can be obtained from our procurement partners in Shared Services:

Head of Procurement (Public Health Wales NHS Trusts)
NHS Wales Shared Services Partnership
Companies House
Crown Way
Cardiff CF14 3UZ

ProcurementServicesenquiries@wales.nhs.uk

Medical equipment purchased for use within Public Health Wales where appropriate is subjected to Risk Assessment during procurement. All Equipment must comply with infection control requirements. Any Public Health Wales agreed standardisation of brands of equipment is compiled with to ensure staff are familiar with the equipment and equipment is comparable with existing devices and to reduce unwarranted variation. Where possible devices are standardised throughout the organisation unless there is a valid clinical reason for the change. Equipment must represent optimal value for money. All devices carry a CE Mark indicating that the Device has been manufactured to the appropriate standard and that it is fit for purpose when used as instructed.

9 Infection, Prevention and Control

9.1 Decontamination

Decontamination will be carried out in line with the relevant Infection, Prevention and Control of Infection policies including the Decontamination of Medical Devices and Equipment Policy and Procedure, local department Standard Operating Procedures, and the Manufacturer's Instructions for Use for more detailed guidance on decontamination of specific devices. Specialist advice can be sought from the organisation's Lead Nurse for Corporate Infection Prevention & Control.

Adherence to manufacturers guidance is required in decontaminating reusable devices. The exact method of the decontamination will vary and the level of decontamination (cleaning, disinfection, and sterilisation) will depend on the level of risk then into decontamination risk assessment.

Guidance should be sought at the tendering stage of procurement from the manufacturer concerning decontamination (cleaning, disinfection, sterilisation), to ensure the manufacturer's instructions can be met within organisational policies and existing facilities.

Advice should be supplied and verified as suitable at the acceptance stage for new or loaned equipment.

9.2 Operating Policies (SOPs)

A record of decontamination of all medical devices must be held by individual areas in order to provide assurances that equipment has been decontaminated in accordance with legislation and guidance. Decontamination certificates should be issued prior to service maintenance or repair by any department or company. Unless the accepting company has issued written communication to say this is not necessary.

9.3 Single Use Items

Medical devices designated for single use are not re-used under any circumstances. MDA DB 2000 (04) draws attention to the hazards and risks associated with re-processing and re-using single use items – see Infection Prevention Control Policy. Single use means that the manufacturer:

(a) intends the item to be used once, then thrown away

(b) considers the item unsuitable for use on more than one occasion

(c) has insufficient evidence to confirm that re-use would be safe

Single use medical devices should not be re-used as this affects the safety, performance and effectiveness of the device, and exposes staff and service users to unnecessary risk.

There is a European Standard Symbol used on packaging to show which medical devices are intended for single use only. All staff involved in the decontamination process should understand this symbol and its meaning.

There is a European Standard Symbol used on packaging to show which medical devices are intended for single use only. All staff involved in the decontamination process should understand this symbol and its meaning.

Please note:
The Consumer Protection Act 1987 will hold a person liable if a single use item is re-used against the manufacturer's recommendation. Attempts to decontaminate single use items would render the organisation liable in the event of an adverse outcome.

10 Prescription of Devices

The Prescription of Devices is the selection of the most appropriate device to use for a given situation and will only be made by staff with the appropriate professional qualifications. Competency to prescribe must be assessed, recorded and audited to ensure consistency and accuracy of prescribing procedures.

Technical support and advice is available from relevant Maintenance Departments, Infection Control Nurse and Procurement together with relevant external agencies i.e. MHRA, WHE.

11 Device Acceptance Procedures

Each Division will need to have acceptance testing arrangements in place and these should be in accordance with the guidelines contained in section 5 of MHRA DB9801 and DB2003.

For portable equipment, a variety of acceptance testing procedures may be necessary – electrical safety tests, for example.

11.1 Planned Preventative Maintenance (PPM)

Divisions should have arrangements in place for planned preventative maintenance of medical devices and equipment and relevant staff should be aware of maintenance procedures including timescales for maintenance checks based on the manufacturer's recommendations. How the device is used and how often must also be considered when determining service intervals.

11.2 Storage of Devices

It is important that adequate storage arrangements are in place for safely storing equipment including accessories.

11.3 Maintenance and Repair of Medical Devices

Medical devices must be kept safe and effective, through both routine maintenance procedures, supervised by professional users, and planned preventative maintenance by suitably trained technical staff. All maintenance and equipment management will be undertaken using the guidelines contained in MHRA guidance DB9801 and any other relevant publications.

Each Division must ensure that maintenance is carried out by suitably qualified staff whether internal or external.

11.4 Routine Maintenance by Users

Routine maintenance by users should ensure that the device continues to function correctly. It entails regular inspection and care, as recommended by the manufacturer or within local procedures. This should clearly show the routine tasks and how they should be carried out. Instructions for the user maintenance of medical devices should be provided to the user, which should include:

- Checking that it is working correctly before use
- Regular cleaning
- Specific daily / weekly checks
- Noting when it has stopped working properly or when obvious damage has occurred, and then discontinuing use
- Reporting or arranging for servicing as per local procedures

Users may need to be trained to carry out routine maintenance.

12 Use of Medical Equipment for Non-designated Purpose

It should be noted that modification of equipment or use of any equipment for other than its intended purpose is a clear breach of the terms of the manufacturer's warranty. If a service user, carer or staff suffers harm in the process, the liability will not fall to the manufacturer.

Where a modification confers benefit, a fully documented risk assessment should be undertaken and risk management process defined before seeking approval from the MDMG.

13 Loan Equipment Procedures

- Equipment Loaned from Others for Trials or other purpose (internal / external)
- Loaned from a manufacturer or supplier
- Loaned from another organisation
- Loaned for research purposes

All borrowed devices must go through the same acceptance procedure/acceptance tests as new equipment. The same standards of training, competence, maintenance, repair and calibration apply to loaned, trial or purchased equipment.

In all cases, a Loan Indemnity agreement must be completed as a record for Public Health Wales or check if a blanket agreement has been signed by the supplier which may need to be used against any incident resulting from faulty equipment.

It is important that at the end of its loan period the equipment is removed from use or accepted as part of the inventory of equipment. Should it cease to be on loan but still in use, full responsibility must be assumed for the equipment and its acquisition treated as if it were new equipment.

13.1 Internal Loans

When a piece of equipment is loaned to another department, it is the responsibility of the borrower to ensure that they have been trained and are competent to use the equipment. The borrower will be responsible for and be aware of the maintenance/care requirements whilst in their possession and must ensure the device is returned in safe working order having been cleaned/decontaminated/sterilised as appropriate.

13.2 External Loans to Carers / Patients

In exceptional circumstances only equipment may be loaned to patients/carers as part of their on-going care needs or as part of their treatment.

It is important to assess whether those being loaned the equipment are capable of taking responsibility for it, i.e. that they are competent to use and maintain the equipment and will return it in good condition.

14 Adverse Incidents (Device Related)

An incident is any unplanned event which leads to an undesirable effect on Public Health Wales. This can include effects on service users, staff, visitors, members of the public, premises or property and other assets.

It is the responsibility of all staff to report any events which occur without undue delay through Datix Cloud. Should staff identify any medical devise incidents, they must be reported in accordance with the Incident Reporting and Management Procedure and recorded on the Datix system. This is to ensure that there is oversight of all medical device related incidents and to align to the organisations Health & Safety obligations.

14.1 Reporting Medical Device Incidents on Datix

The NHS in Wales uses an electronic risk management system called "DATIX Cymru" and all incidents should be reported using the incident reporting form on Datix. This can be accessed through PHW intranet home page here.

The information provided in the Datix Incident should provide as much information as possible regarding what has occurred, and the immediate actions undertaken. It should be:

- Free from abbreviations
- The name of the medical device involved (not names used that are used colloquially) is to be provided
- If possible, it should include the serial number and equipment ID – this is included in "equipment section" of the reporting form
- Inform the person reading the description what the impact of this incident occurring is

A flowchart is available at Appendix 1 to highlight the process for reporting an incident.

All medical devices incidents are reported to the Medical Devices Management Group for governance and oversight. It is important that all Medical Devices incidents are reported on Datix to ensure reporting is accurate and any trends/themes can be easily identified and monitored.

15 Decommissioning and disposal of devices

15.1 Replacement Criteria

In consideration of fiscal circumstances medical devices/equipment will be replaced, following consideration, by the users and where appropriate if appointed Divisional Medical Device Co-ordinator, on the following criteria:

- Worn out beyond economic repair
- Damaged beyond economic repair
- Unreliability (Service History)

- Clinically or technically obsolete
- Spare parts (manufacturers support) no longer available
- More cost-effective or clinically effective devices have become available
- Unable to be cleaned effectively prior to disinfection and/or sterilisation
- Medicines and Healthcare products Regulatory Agency (MHRA) notification-Hazards etc

15.2 Disposal / Transfer of Ownership of Equipment

The purpose of this section is to ensure that all equipment is disposed of with due regard to safety and to ensure managers consider appropriate legal implications.

15.3 Financial Considerations

All equipment sold or disposed of must be done so in accordance with relevant Welsh Government circulars and Public Health Wales' Corporate Governance and Finance Policies to ensure financial probity and in consideration of any capital charges which may be relevant. Disposal of equipment should comply with the Procedure for the Disposal of Obsolete and Surplus Equipment.

Failure to follow appropriate guidance or legislation when selling medical devices and other equipment could lead to prosecution or liability for damages.

All equipment should be disposed of or sold/donated in accordance with:

- Department of Health Guidance HN89(22)
- MHRA Guidance DB9801 supplement Two

15.4 Public Health Wales' Liabilities When Ownership is transferred

In the event of a sale or donation all new owners must sign a disclaimer to limit any future legal liabilities of the organisation. It should be noted however that this disclaimer does not absolve the organisation of all legal liabilities and could still be left liable to prosecution e.g. where negligence *can* be proven. In general the more comprehensive the information supplied to the new owner the more the organisation's liability is reduced.

15.5 Information to be supplied to New Owner

Manufacturer's instructions and any other information needed to verify whether the medical device can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration

needed to ensure that the device operates properly and safely should be provided to the new owners.

The new owner should also be furnished with any safety information provided by the Medicines and Healthcare products Regulatory Agency (MHRA) such as product safety updates. The new owner should also be advised to regularly check if there are any future product updates.

As a minimum, the following information should be provided:

- Record of any reconditioning work carried out, including a record of replacement parts
- Copy of all maintenance and servicing that has been carried out including the name of maintenance / servicing organisation
- Record of usage
- Fault log
- Decontamination status

16 Confidentiality

Some equipment may have the capacity to hold electronic information which may compromise a patient's confidentiality. Any such equipment will have memories fully erased or data storage / retrieval capacity destroyed before disposal or transfer of ownership in accordance with IT policies.

Computer system hard drives must be wiped/erased to a recognised standard to ensure no Personal Identifiable Information (PII) or organisational information is retained within the system.

17 Training requirements

17.1 Training of Staff in the Use of Clinical Equipment

Training of staff in the use of medical devices equipment is essential if the organisation is to ensure that the health care workers it employs are competent to undertake the duties for which they are employed and to ensure that the potential risk of harm to patients is reduced to a minimum.

This section applies to all grades and disciplines of staff that are employed directly or indirectly within relevant divisions.

17.2 Identification of Training Need

All departments will identify equipment within their areas for which staff will require specialist training; Department managers will identify which staff are able to use each device following successful completion of a programme of training. This may include setting up a device, preparing

for its use, checking the device and decontamination where appropriate.

Consideration must be given to the possible need to develop new Standard Operating Procedures.

18 Training

Training for *medical devices* will be available via several mechanisms:

- Staff induction
- Device specific training from the device manufacturers
- Device specific training local lead clinicians/educators

Competence should be measured, documentation maintained and training recorded and reviewed as part of staff's individual My Contribution. An appropriate designated storage place for manufacturer's instruction manuals must be specified (this may be electronic or paper).

Review training plans and organise regular refresher training when necessary.

Ensure training / induction includes an understanding of relationships with other departments (e.g., Maintenance Department, Prevention and Control of Infection etc).

Individuals are responsible for ensuring they are competent for any equipment they use. Anyone who does not feel competent must not use equipment until they have undertaken the appropriate training and assessment.

Competence will be monitored and reviewed through staff appraisal and risk management processes or when staff have not used a piece of equipment for 12 months or earlier if indicated by clinical practice.

19 Monitoring compliance

19.1 Maintenance

Service Divisions must ensure that there is adequate maintenance and repair provision for medical devices and equipment and appropriate maintenance and repair schedules are put in place. This should include planned preventative maintenance programmes.

The following should be considered where appropriate:

- Ensure service contracts are in place and establish follow-up systems to ensure contracts are reviewed well before renewal date to ensure best value is achieved
- Devise and monitor systems to ensure equipment which is loaned to patients / other departments etc., is regularly tested for safety and appropriately maintained
- Set up and monitor systems to ensure that maintenance contracts are carried out to the required standard
- A suitable anti-virus product must be installed to any associated computer system and maintained to a current level to protect against all identified vulnerabilities

19.2 Audit

Random audits should be carried out locally on all elements of appropriate use, decontamination, maintenance, repair, record generation and storage to ensure that the correct procedures are in place and being adhered to. Audits should be carried out by staff with appropriate knowledge and experience of managing medical devices. The results of these audits will be reported to the MDMG.

The application of the policy/procedure should be regularly reviewed to ensure that, whenever a medical device is used, it is:

- Suitable for its intended purpose
- Used in line with the manufacturer's instructions
- Traceable, where possible:
    - Maintained in a safe and reliable condition, with associated records kept
    - Disposed of appropriately at the end of its useful life

20 References

- MDA DB9801-February 1999- Medical Device and Equipment Management for Hospital and Community-based Organisations
- MDA DB9801-December 1999- Supplement 1- Checks and Tests for Newly Delivered Medical Devices
- MDA DB9801-October 2001- Supplement 2-Guidance on the Sale, Transfer of Ownership and Disposal of Used Medical Devices
- MDA DB2000(02)-June 2000- Medical Devices and Equipment Management: Repair and Maintenance Provision
- MDA DB2002(02)-March 2002- Management of In-Vitro Diagnostic Medical Devices
- MDA DB2002(03)-March 2002- Management and Use of IVD Point of Care Test Devices
- MDA DB2000(04)-August 2000- Single-Use Medical Devices: Implications and Consequences of Re-use
- National Audit Office Report HC475: -June 1999- The Management of Medical Equipment in NHS Acute Trusts in England
- MDA-The Report of the Expert Working Group on Alarms on Clinical Monitors:-February 1995- In response to Recommendation 11 of the Clothier report: The Allitt Inquiry
- NHS Executive-December 2001- Controls Assurance Standard-Medical Devices Management
- NHS Executive HSC 1999/178. 1999 Variant Creutzfeldt-Jacob Disease (vCJD): Minimising the Risk of Transmission
- DB2003(05) HSG(93)26-June 1993-Decontamination of Equipment Prior to Inspection, service or repair
- Medical Devices Agency-Devices in Practice-a guide for health and social care professionals

Appendix 1 – Incident Reporting Process