

Title:	Medical Devices Procedures and Guidelines		
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Sept 2011	2.0	[Redacted] R. Henry	Various sections updated to clarify and amend current arrangements including indemnity, and disposal of equipment Consultation with MDAC members
Jan 2014	3.0	[Redacted] R. Henry	Consultation with MDAC members Guidance on dealing with medical device company representatives, updating of other sections including indemnity forms, NIAIC reporting, more robust references to DEC's, clarification of various engineering departments, patient data confidentiality
Feb-May 2017	4.0	[Redacted] R Henry Estates/Harry Gordon ICT/Jill Nicholson	Lifecycle diagram revised Delivery Checks (Table 5.1 from MHRA Managing Medical Devices) Safety and calibration checks (Table 5.2 from MHRA Managing Medical Devices) Section on Medical Devices Supplier Representatives revised (§2.4.13) Update of indemnity forms to 2017 versions for equipment on loan Extensive revision of pre-procurement checklist New section on Data security and ICT requirements Revision of section on charitable donations of equipment Revision of section on condemnation and decommissioning Update of Form 3 registration/ acceptance Update of safety alerts to ISPs New Contacts list

1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background

Medical Devices are an integral part of the diagnosis, treatment, support and care of patients & clients. As part of an overall strategy for risk management the Trust has an obligation to make certain that it minimises the risks of using medical devices & equipment to as low a level as practicable. This may be achieved by ensuring that it buys the most appropriate equipment for purpose, trains staff how to use them competently and safely, clean and maintain them correctly and dispose of them in an appropriate manner.

1.2 Purpose

The Trust recognises the risks to patients, clients, staff and others created by the use of medical devices. It therefore intends to ensure that there is a suitable strategic and operational system in place to manage the procurement, usage, maintenance and disposal of medical equipment, to meet the requirements of national legislation and NHS guidance and to make sure that equipment is used safely, competently and effectively for the care of patients.

CONSULTATION PROCESS

Update to existing policy. Formal consultation with Medical Devices Advisory Group (Trust wide multi-disciplinary group responsible for overseeing systems and processes for the management of medical devices).

EQUALITY STATEMENT

In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998), Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, an initial screening exercise to ascertain if this policy should be subject to a full impact assessment has been carried out.

The outcome of the Equality screening for this policy is:

Major impact

Minor impact

No impact. X

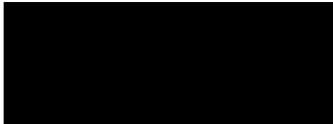
SIGNATORIES

(Policy – Guidance should be signed off by the author of the policy and the identified responsible director).



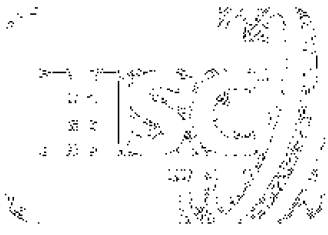
Dr Cathy Jack,
Medical Director

Date: _____**July 2017**_____



Martin Dillon
Chief Executive

Date: _____**July 2017**_____



**Belfast Health and
Social Care Trust**

Medical Devices Procedures & Guidelines

Procedures & Guidelines for the Management of Medical Devices

Contents

1. <u>Introduction</u>	9
1.1. Relationship to Medical Devices Policy	9
1.2. Definitions	10
1.2.1. Medical Device	
1.2.2. Medical Equipment	
1.2.3. End User	
1.2.4. Professional User	
1.2.5. Prescriber	
1.2.6. Department Equipment Controller	
1.2.7. Department Equipment Assistant	
1.2.8. User Servicing	
1.3. Management structure	11
1.4. Roles and Responsibilities	11
1.4.1. Trust Board	
1.4.2. Medical Devices Advisory Committee	
1.4.3. Senior Manager Corporate Governance	
1.4.4. Medical Devices Manager	
1.4.5. Medical Devices Coordinator	
1.4.6. Department Equipment Controller	
1.4.7. Department Equipment Assistant	
1.4.8. Community Loan Stores Manager	
1.4.9. Community Loan Stores Storeman	
1.4.10. Technical Supervisor	
1.4.11. Estate Services	
1.4.12. Medical Devices Advisory Committee Subcommittees	
1.4.12.1. Directorates Medical Devices Committees	
1.4.12.2. POCT Subcommittee	
1.4.12.3. Decontamination Operational Group	
1.4.12.4. Management of Medical Devices in Community Settings Group	
1.4.12.5. Ad Hoc Subcommittees	
1.4.13. Estate Services	16
1.5. Record keeping - Management of Medical Devices Folder	17
2. <u>Procurement</u>	18
2.1. Procurement Management	18
2.2. Justification of Need	18
2.3. Financial Approval	18
2.3.1. Devices Valued at less than £5000	
2.3.2. Devices Valued at £ 5000 or greater	
2.3.3. Free issues of medical equipment and donations	
2.4. Selection	19
2.4.1. User Requirements	

2.4.2.	Technical Standards	
2.4.3.	Decontamination Standards	
2.4.4.	Device Standardisation	
2.4.5.	Building Services Requirements	
2.4.6.	Specialist Liaison	
2.4.7.	Data Security and ICT Requirements	
2.4.8.	Acceptance/Performance testing	
2.4.9.	Finance Services	
2.4.10.	Competitive Quotations and Tenders	
2.4.11.	Maintenance Requirements and Availability of Support	
2.4.12.	Training Implications	
2.4.13.	Total Whole Life Costs	
2.4.14.	Medical Devices Supplier Representatives	
2.5.	Manufacturer's Instructions	23
2.5.1.	<i>Procurement checklist</i>	
2.5.2.	<i>POCT Procurement checklist</i>	
3.	<u>Putting into Service</u>	24
3.1.	Delivery Checks	24
3.2.	Acceptance Testing	24
3.3.	Installation and Release of New Devices	24
3.4.	Medical Devices Acceptance	25
3.4.1.	<i>Medical Devices Registration/Acceptance Form</i>	
3.4.2.	<i>Department Inventory Form</i>	
3.5.	Equipment Registration on asset register	26
3.6.	Storage of New Devices	27
3.7.	Prescription of Medical Devices	27
3.8.	Medical Devices on Trial or on Loan into the Trust	27
3.8.1.	<i>Trial/Loan Indemnity Forms</i>	
3.9.	Medical Devices on Loan to Patients	31
3.9.1.	<i>Record of equipment on loan to patient/client/carer</i>	
3.9.2.	<i>Checklist for patients discharged with a medical device</i>	
3.10.	Modifications	33
3.11.	In-house Medical Device Manufacture	33
3.12.	Research/Clinical Studies and Medical Devices	32
4.	<u>Training</u>	35
4.1.	Generic training	35
4.2.	Specific training	35
4.2.1.	<i>Equipment Training & Familiarisation Schedule</i>	
4.2.2.	<i>Medical Device Training Record - department</i>	
4.2.3.	<i>Medical Device Training Record – personal record</i>	
4.3.	Statement of Practice	36
4.4.	Defined Training Requirements	37
4.4.1.	General Use – Low to Medium Risk Medical Devices	
4.4.2.	General Use – High Risk Medical Devices	
4.4.3.	Specialist Areas Use	
4.5.	Instructions for Use	38
4.5.1.	Instructions for professional users	

4.5.2. Updates of instructions	
4.5.3. Instructions for end users	
5. <u>Decontamination</u>	40
5.1. Management Responsibilities	40
5.2. Specific guidelines for decontamination of invasive medical devices	41
5.3. Handling of invasive medical devices on loan from another organisation	41
5.3.1. <i>Declaration of Contamination Status (Decontamination certificate)</i>	
Medical & Nursing equipment cleaning guide	43
6. <u>Servicing & Maintenance</u>	44
6.1. User Servicing (Routine Maintenance)	44
6.2. Scheduled Servicing (PPM - Planned Preventative Maintenance)	45
6.3. Unscheduled Servicing ((Emergency Repairs/Breakdown Servicing)	45
6.4. Reporting Breakdowns	45
6.4.1. Where Estate Services Arrange Maintenance & Repair	
6.4.2. Where Directorate Staff Arrange Maintenance & Repair	
6.5. Trust in-house Service/Technical Departments	45
6.6. Decontamination before Servicing & Repair	46
6.6.1. Routine decontamination procedures	
6.6.2. Decontamination for servicing or repair	
6.7. Devices Returned to Manufacturers	46
6.7.1. <i>Declaration of Contamination status (Decontamination Certificate)</i>	
6.8. Single Use Devices	47
7. <u>Transfer and Disposal</u>	48
7.1. Replacement of Equipment	48
7.2. Deletion of patient sensitive data	48
7.3. Decommissioning	48
7.4. Condemning	48
7.4.1. Devices Being Permanently Taken Out of Service	
7.4.2. Devices Being Temporarily Taken Out of Service	
7.5. Disposal	49
7.5.1. Devices being Permanently Taken Out of Service	
7.5.2. Devices Being Temporarily Taken Out of Service	
7.6. Transfer of Old or Obsolete Devices	49
7.6.1. <i>Condemnation & Disposal Record</i>	
7.6.2. <i>Checklist for Sale or Transfer of Ownership of a Used Medical Device</i>	
7.6.3. <i>Disclaimer for Disposal Of Equipment Surplus to Requirement</i>	
7.6.4. <i>Permit for Removal Of Obsolete Equipment From Belfast Trust Hospital Site</i>	
8. <u>Medical Device Vigilance</u>	51
8.1. <u>Adverse Incidents Procedures</u>	51
8.2. <u>Distribution of Medical Device Alerts & other Safety Alerts</u>	54

Appendices	56
1. <u>Medical Devices Advisory Committee Remit</u>	57
2. <u>Role definitions</u>	59
2.1. Medical Devices Manager's responsibilities	
2.2. Medical Devices Coordinator's responsibilities	
2.3. Department Equipment Controller's responsibilities	
2.4. Department Equipment Assistant's responsibilities	
2.5. Community Equipment Loans Store Manager	
2.6. Community Equipment Loans Storeman	
2.7. Technical Supervisor's responsibilities	
3. <u>Forms</u>	
1. <u>Procurement</u>	
a. <u>Equipment Procurement Checklist</u>	65
b. <u>POCT Procurement Checklist</u>	70
2. <u>PPQ – Pre-Purchase Questionnaire</u>	73
3. <u>Part A - Registration/Acceptance form</u>	75
<u>Part B - Details of Acceptance Procedure for</u>	
<u>Newly Delivered Devices</u>	76
<u>Part C - Maintenance Contract Request Form</u>	77
4. <u>Ward/department Inventory Record of Medical Device</u>	82
5. <u>Trial/Loans Indemnity Guidance</u>	83
Form 5a - <u>Overarching Master Indemnity Agreement</u>	87
Form 5b - <u>Mia Call-Off Agreement</u>	89
6. <u>Record of Equipment on Loan to Patient/Client/Carer</u>	93
7. <u>Equipment Training and Familiarisation Schedule</u>	94
8. <u>Medical Device Training Record – Department Record</u>	95
9. <u>Medical Device Training Record – Personal Record</u>	96
10. <u>Part A - Decontamination Guidance</u>	97
<u>Part B - Declaration of Contamination Status (Decon Certificate)</u>	99
11. <u>Condemnation & Disposal Record</u>	100
12. <u>Checklist for Sale or Transfer of Ownership of a Used Medical Device</u>	101
13. <u>Disclaimer for Disposal of Equipment Surplus to Requirement</u>	102
14. <u>Permit for Removal of Obsolete Equipment from Belfast Trust</u>	
a. <u>Hospital Site</u>	103
15. <u>NIAIC Adverse Incident Report Form</u>	104
<u>Useful Contacts</u>	105
<u>References</u>	106
<u>Belfast Trust Policies</u>	107

1 Introduction

1.1 Relationship to Medical Devices Policy

Medical Devices are an integral part of the diagnosis, treatment, support and care of patients. As part of an overall strategy for risk management the Trust has an obligation to make certain that it minimises the risks of using medical devices to as low a level as practicable by ensuring that it buys the most appropriate equipment for purpose, trains staff how to use it competently and safely, cleans and maintains it correctly, and disposes of it in an appropriate manner.

This will be managed by controlling each phase of the device lifecycle as illustrated in figure 1 below

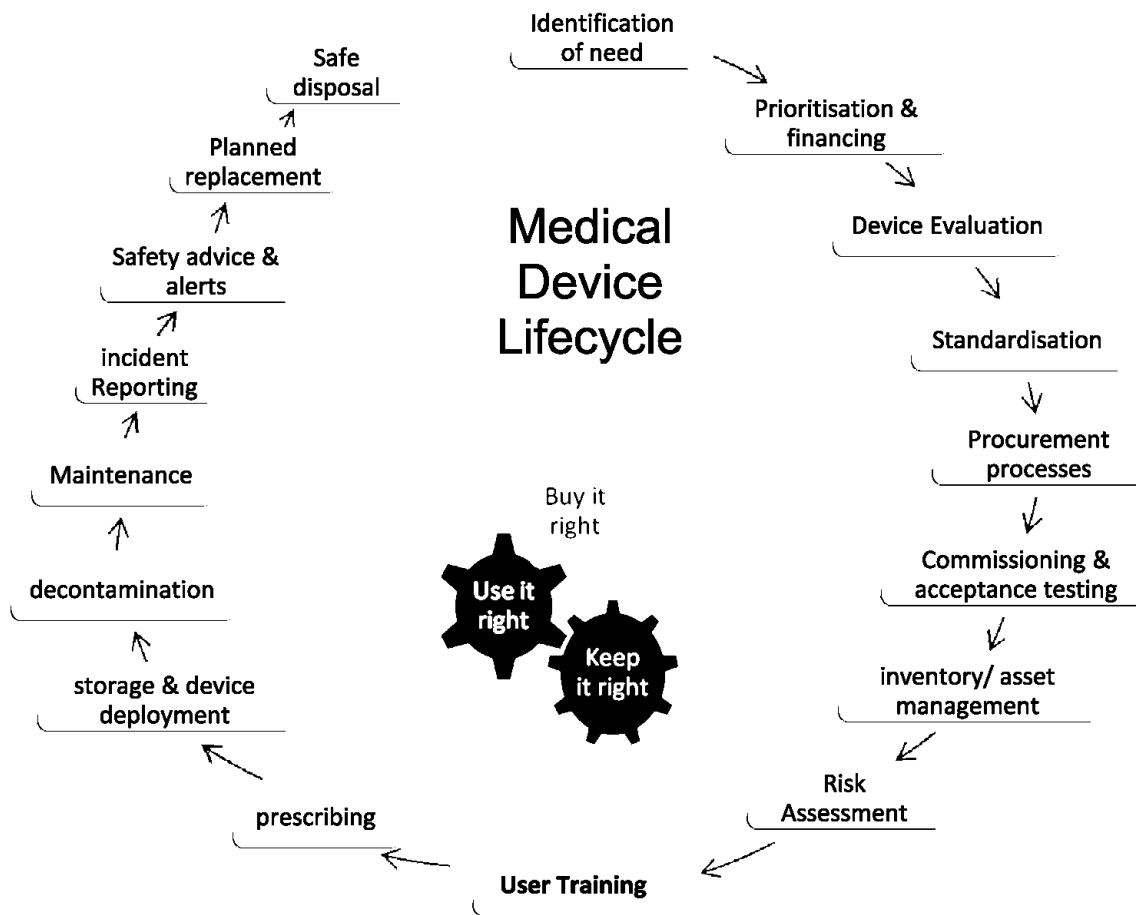


Figure 1

These principles are embodied in the Trust's Medical Devices Policy and the following Procedures & Guidelines contained in this document give direction on how this can be achieved in practice.

1.2. Definitions

1.2.1. Medical Device

The term covers a broad range of products including those used every day in most health care settings. As defined by the Medical Devices Directive, Medical Device means:

“An instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which is intended by the manufacturer to be used for human beings for the purpose of –

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

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means.”

The definition covers a vast range of products ranging from dressings to x-ray machines.

Not all guidance given in these procedures will be applicable to every medical device but this will generally be self-evident.

1.2.2. Medical Equipment

The term medical equipment refers to products that are not medical devices as defined by the Medical Devices Directive but are used in association with Health and Social Care (e.g. chair lifts, fluid warming cabinets and disinfecting and sterilizing equipment). The management procedures are generally the same as for medical devices and any differences will be specifically highlighted.

For the purposes of this document the term ‘medical device’ can be taken to include ‘medical equipment’ unless otherwise stated.

1.2.3. End User

A person who uses a device on or for themselves, as distinct from a professional user.

1.2.4. Professional User

The professional user is a trained and qualified member of Trust staff who operates a medical device for the benefit of a patient or client, on behalf of the responsible organisation.

1.2.5. Prescriber

A person who decides which is an appropriate Medical Device or item of equipment for a given patient or client (e.g. doctor, nurse, AHP etc.).

1.2.6. Department Equipment Controller

Ward/department/service area manager or deputy responsible for procurement, asset management, record-keeping, servicing/maintenance and assisting onward reporting of incidents involving devices.

1.2.7. Department Equipment Assistant

Ward/department staff member(s) responsible for on going care of medical devices including user servicing, appropriate storage, checking of inventory and return of loan devices.

1.2.8. User Servicing

Simple routine maintenance such as checking or cleaning that can be carried out on a regular basis by all users with a minimum of specialised training.

1.2.9. Technical Supervisor

Staff members with technical or managerial role in devices or equipment management. They can be in charge of acceptance testing, installation, repair, maintenance or decontamination; e.g. estates officer, biomedical engineer, critical care scientists, Sterile Services manager, etc

1.3 Management structure

See appendix 2, figure 1

1.4. Roles and Responsibilities

Roles and responsibilities are summarised in this section and detailed in Appendix 2.

1.4.1. Trust Board

The Chief Executive has overall responsibility for the management of medical devices/equipment within this Trust, and the Medical Director is the designated accountable officer with responsibility for medical device and equipment management.

Both the Chief Executive and Medical Director are responsible for implementation and maintenance of statutory requirements within all locations where medical devices/equipment are used.

1.4.2 Medical Devices Advisory Committee

A broad based Medical Devices Advisory Committee operates within the Trust to promote and co-ordinate medical devices and equipment management. Its remit is detailed in appendix 1.

1.4.3 Senior Manager Corporate Governance

Responsible through the Co-Director Risk and Governance for the development and implementation of a Controls Assurance Standard programme and will co-ordinate the Trust's response to the annual self-assessment. Support in the maintenance and continual review of the Trust's risk register and assurance framework.

They will act as the Trust's MDLO (Medical Devices Liaison Officer) with NIAIC and will be responsible for monitoring incidents involving medical devices, forwarding appropriate reports to NIAIC and for managing the initial distribution and collated responses of safety alerts involving medical device.

They will act as the Trust lead within Corporate governance for the monitoring of compliance with the decontamination of reusable medical devices.

They will support the Co Director in the co-ordination of reports and responses to statutory and other external bodies such as the DHSSPS and the RQIA.

1.4.4 Medical Devices Manager

The in-house expert on Medical Device Management, responsible through the Senior Manager Corporate Governance Services for the development of robust governance processes for the effective and safe management of medical devices including their decontamination. Responsibilities are detailed in appendix 2, 2.1

1.4.5 Medical Devices Coordinator

Support and assist the Medical Devices Manager in the management of medical devices including their decontamination. Assist with the appropriate dissemination of Safety Alerts and monitoring of returns. Responsibilities are detailed in appendix 2, 2.2

1.4.6 Service Manager

It is the responsibility of all service managers to make sure that DEC's (Department Equipment Controllers) are identified and in place for all relevant clinical areas within their remit

1.4.7 Departmental Equipment Controller

The Departmental Equipment Controller (the Ward/Department manager or designated senior staff member) is responsible for the management of medical equipment within their area. Their duties include:

- Completion and maintenance of an up-to-date inventory of equipment held in their department
- Involvement in commissioning of equipment for their department
- Upkeep of records on inventory & service history of equipment
- Ensuring correct installation of equipment, availability of manuals & training
- Ensuring that a maintenance regime is in place. Liaison with Technical Supervisor/Estates Department to ensure relevant maintenance contract has been raised and regular monitoring and servicing is carried out as per specifications
- Identify convenient time for servicing
- Liaison with such other departments as may be required for successful management of medical devices under their remit, e.g. ICT, Estates, laboratories, POCT, etc.

1.4.8 Equipment Assistant

There should be at least one Equipment Assistant for each department, ward or other area where medical equipment is used. This may be a healthcare assistant or equivalent role.

The Department Equipment Assistant is responsible for assisting the Department Equipment Controller with the following;

- checking of equipment on a periodic basis for inventory purposes,
- visual inspection of defects
- facilitating and recording return of on-loan devices
- user servicing as required e.g. cleaning, battery changes, calibration

Where extra training is required this shall be organised by the Trust

1.4.9 Community Equipment Loan Stores Manager

The Community Loan stores Manager is responsible for the management of medical equipment within their area. Their duties include:

- Management of the database holding the information of medical devices in the community to ensure traceability
- Involvement in the procurement of equipment to be delivered by the department
- Ensuring the service engineers receive accurate lists of equipment requiring servicing at the recommended intervals
- Ensuring that new equipment is assessed and added to service lists if necessary
- Ensuring staff receive appropriate training to ensure correct installation of equipment
- Providing a source of technical advice

1.4.10 Community Equipment Loan Store Storeman

The Community Loans Store Storeman is responsible to the Community Loans Store manager for the following;

- Decontamination of equipment and checking to see if it is fit for issue
- Reporting defects or possible areas of concern with equipment
- Ensuring equipment is appropriately labelled as Trust property and with serial number
- Checking new equipment delivered to the store
- Arranging repair of equipment
- Completion of all relevant documentation
- Recommend to Manager any equipment that should be condemned

1.4.11 Technical Supervisor

This is a person in charge of acceptance testing, installation, decontamination, maintenance and/or repair (e.g. biomedical engineering /medical physics department manager or community stores staff). They may be responsible directly for this work or designate others to undertake it as appropriate

1.4.12 Medical Devices Advisory Committee Subcommittees

1.4.12.1 Directorate Medical Devices Committees

All specific medical devices & equipment, including those under commercial ownership, must be assigned to a specified *Directorate*. The Director has overall responsibility for ensuring the Trust's policy is implemented in relation to the management of medical devices & equipment within their *Directorate*. *Directorate* management responsibilities include procurement, training, maintenance, decontamination and disposal. The responsibility also covers health and safety matters related to medical devices and equipment, and liaison with such other departments as may be necessary e.g. laboratories, ICT, estates etc.

Within each *Directorate* there should be a group responsible for managing specific issues and responsibilities with regard to Medical Devices. The responsibilities for these functions are set out in Appendix 2.

This may be a dedicated Medical Devices committee or a subgroup of another *Directorate* committee such as Risk Management or Assurance Committee.

This group may include representatives from the following, as applicable:

- Directorate Quality & Governance manager
- Clinical /professional groups representatives including nursing, medical, AHPs, imaging, etc
- Medical technical officer representative
- Decontamination representative
- Infection prevention control representative (link nurse)
- POCT/Labs as applicable

- ICT as applicable
- Estates as applicable

The role of the 'Technical Supervisor' must also be covered for each *Directorate* either by Estate Services and/or suitably qualified staff within the *Directorate*. Where Technical Supervisor duties are shared between Estate Services and a *Directorate*, responsibilities must be clearly defined.

1.4.12.2 POCT (Point of Care Testing) Subcommittee

Terms of Reference

Introduction

The Point of Care Testing Committee is a subgroup of the Medical Devices Advisory Committee, and has been approved as such by Dr Stevens, Executive Chair of the Committee.

Main Purpose

- To advance knowledge of POCT practices in Belfast Health and Social Care Trust
- To improve patient care by applying Quality Assurance and Total Quality Management principles, in utilisation of the POCT programs
- To promote communication and co-operation between professional group directly and indirectly involved in the POCT systems and programs
- To assist in implementing the protocol for new POCT requests and procedures

Main functions

This committee shall:

1. Ensure that the responsibilities and authorities necessary for quality management of POCT are defined and communicated within the Belfast Health and Social Care Trust
2. Assist in evaluating and selecting POCT equipment and systems, using defined health care and patient outcomes consistent with the Regional Consensus Policy for POCT Testing in Northern Ireland, the Medical Devices Agency Device Bulletin (MDA DB2002(03), and the Joint Working Group on Quality Assurance guidelines¹
3. Evaluate and approve end-user POCT proposals for the installation of POCT equipment
4. Designate staff responsible for POCT in the various patient care areas
5. Ensure that appropriate systems are in place for:
 - Monitoring the training, certification and re-certification of POCT system operators
 - Maintenance of equipment and supply of consumables and reagents
 - Appropriate quality assurance and record keeping
 - Security from unauthorised or inappropriate use of POCT devices
6. Provide input for the identification of POCT improvement opportunities including equipment upgrades and replacement, connectivity options, documentation requirements.
7. Advise changes to POCT policies, processes and procedures when appropriate.
8. Participate in the review of External Quality Assessments (Quality Management Program – Laboratory Services – RCPA and College of American Pathologists – CAP).

1.4.12.3 Decontamination Operational Group

Terms of Reference

The Belfast HSC Trust has established an Operational Decontamination Group to ensure that systems and processes are in place within the different Service areas and these are reviewed to properly manage decontamination across the range of healthcare provisions. This will take into consideration current best practice and national standards in order to minimise the risk of infection from Medical devices, in particular reusable surgical instruments and endoscopes used in interventional procedures.

The Operation Decontamination Group will meet every four months.

Reporting Arrangements This Group will report to the Medical Devices Advisory Committee and provide a report for each Medical Devices Advisory Committee meeting.

The Operational Decontamination Group will:

- Co-ordinate or undertake work at the request of the Medical Devices Advisory Committee.
- Provide a forum to discuss and agree forward action regarding Trust-wide Decontamination issues.
- Assist the Medical Devices Advisory Committee in the implementation of strategy to ensure that decontamination, best practice and national standards are achieved and maintained. This will include a programme of audit, inspection, provision of policy, guidelines and training.
- Provide advice concerning appropriate consideration of Medical device and equipment purchasing/acquisition issues in relation to decontamination and comparisons of alternative medical devices or equipment including where possible standardisation to single models .
- Monitor Decontamination Risks through the Trust risk management processes.
- Establish Decontamination related KPIs and annual reporting on the management of medical devices.
- Review serious untoward incidents involving decontamination ensuring appropriate action is taken and trends identified.
- Ensure Directorates have systems in place to monitor provision of sufficient training for all users who provide a decontamination role.
- Develop a Trust-wide approach to the decontamination of medical devices.
- Provide a source of advice relating to financial data, including consideration of full on costs when preparing a medical device or equipment purchase bid, including disposable and replacement costs.
- Monitor Manufacturer's instructions and training provided across the different service areas.

1.4.12.4 Management of Medical Devices in Community Settings Group

Terms of Reference

Introduction

The Management of Medical Devices in Community Settings Group is a subgroup of the Medical Devices Advisory Committee, and has been approved as such by Dr T Stevens, Executive Chair of the Committee.

Main Purpose

To consider from a Community Services perspective all issues relating to the management of medical devices. This will include device management, communication of medical device information, training, safe operation, incident reporting and audit.

Main functions

This group would be expected to:

- Advance knowledge of the management of medical devices and related practices in community areas within Belfast Health and Social Care Trust.
- Identify and support leads on the management of equipment in the community setting
- Identify responsibility for device management, training, safe operation, maintenance, incident reporting and audit in the community setting.
- promote communication and co-operation between professional groups directly and indirectly involved in the use of medical devices within the community setting
- promote knowledge of, and ensure compliance with, The Trust Policy & Procedures on the Management of Medical Devices
- Advise on purchasing & acquisition issues including standardisation
- Monitor reported Incidents involving medical devices and support reporting area to ensure thorough investigation and follow-up, including dissemination of lessons learned.
- Advise on and assist in the appropriate dissemination of Safety Alerts and other guidance on equipment safety issues
- Ensure that staff are trained in and comply with appropriate decontamination of medical devices and equipment
- Ensure that staff complete registration and acceptance procedures for new equipment and that the inventory of medical equipment within the community area is kept up to date
- Oversee the monitoring of Training programmes
- Promote awareness of changes that occur with manufacturers'/suppliers' IFUs (Instructions For Use) and the need to update at local level.
- Provide a quarterly/annual report to the Medical Devices Advisory Committee, as required by that committee
- Monitor those Trust KPIs related to medical devices management such as incident reporting, training and NIAIC MDA (Medical Device Alerts) feedback

1.4.12.5 Ad Hoc Subcommittees

The Medical Devices Advisory Committee may also convene any such temporary or permanent subcommittees or working groups as may be deemed necessary to fulfil its role and functions.

1.4.13 Estate Services

Estate Services may assist, as required, to:

- undertake the Technical Supervisor "role" for Clinical Directorates (See Appendix 2)
- prepare and/or assist in the preparation of technical specifications and drawings, as applicable. The lead in this may be taken by other departments (eg ICT or labs for POCT) as applicable
- cost and manage installations

- undertake Acceptance tests
- assist with training as applicable (e.g. medical engineering department)
- provide a broad “first line” maintenance service as applicable
- provide a full maintenance service on specified devices, either directly or contracted to a 3rd party
- assist with disposal of medical devices

1.5 Record keeping - Management of Medical Devices Folder(s)

The Departmental Equipment Controller (Ward/Department manager or designated senior staff member) is responsible for maintaining records in relation to medical equipment. It is advised that each ward/department should maintain all medical device related records in a single folder, to be known as Management of Medical Devices Folder. This will be similar to the PPM folder (Planned Preventative Maintenance) folder that some areas may have used previously and these can be updated to hold all the recommended records. This includes details of

- Inventory – see section 3
Completion and maintenance of an up-to-date inventory of equipment held in their department
- Training – training programmes, and records of those trained - see section 4
- Equipment documentation including manuals, IFUs (Instructions for Use), SOPs (Standard Operating Procedures), etc. Where possible copies of these should be kept with the equipment itself
- Loans (into or out of department) – see sections 3.8, 3.9
- Service history of equipment – see section 6
This should contain
 - Inspections and routine servicing
 - Repairs
 - Modifications including software or hardware upgrades
 - Faults reported

Other suggested contents of the folder would be a copy of this Medical Devices Policy & Guidelines and spare copies of the forms contained in these Guidelines.

Where departments already have adequate arrangements for maintaining these records then their process should be allowed to continue as long as they support current Trust arrangements, and until such times as the Trust moves from a paper based records to an electronic system. This also includes those departments where local electronic records, e.g. databases, are already in use.

Service areas must ensure that information held on local systems is reflected in the Trust asset management system

2. Procurement

All procurement must be in accordance with the Trust's procedures and follow the DHSS & PS guidance (PPM) 8/2003.

When a medical device is obtained and remains under commercial ownership as in public private partnership, lease or loan contracts there is still a Trust requirement under duty of care and contractual obligations to manage it. Individuals or organisations wishing to donate medical devices must be made aware of the Trust's procurement policy.

All medical devices purchased must bear the CE mark. The CE mark ensures that the product has passed through a common system of regulations for the safety and marketing of the product throughout the European Union and the CE mark is the only mark certifying that products conform to the *Essential Requirements* of the Medical Devices Directives.

In some cases there may be a necessity for equipment that is not available to buy elsewhere, or that is available but not CE-Marked. In these instances it might be possible to have some such equipment fabricated in-house or risk assessed and approved by the Medical Physics department. If this is the case such equipment needs to be presented to, and accepted by the Medical Devices Advisory Committee

The Equipment Procurement checklist (Medical Devices form 1A) gives an extensive though not exhaustive framework of issues to consider when procuring equipment and this checklist is expanded upon in the following sections

2.1 Procurement Management

Input from a number of departments and individuals may be required during the procurement process, e.g. estates for electric or water supplies, or Labs for POCT (Point of Care Testing) equipment. It is recommended that an appropriate person is nominated by the Directorate to oversee the procurement of each capital purchase.

2.2 Justification of Need

Purchase of equipment may be justified for one or more of the following reasons:-

- Statutory safety requirements
- Clinical need/developments
- Existing equipment beyond economic repair or obsolete
- Maintenance support or parts no longer available

2.3 Financial Approval

2.3.1 Devices Valued at less than £ 2000

Purchases will normally be funded from the *Directorate* revenue budget at the discretion of the relevant director.

2.3.2 Devices Valued at £ 2000 or greater

All devices, either a single item or a number of smaller inter-related parts, which together form a unit, and which in total exceed £5,000, are deemed to be capital purchases. The *Directorate* may have to bid for funding through the *Capital Expenditure Control Group* in which case an "Application for Capital/Major Revenue Expenditure Form" should be completed and submitted to the Director of Operational Support's office. The requisite forms are available from the Service Speciality/Area manager or from the Estate Services/Finance Department

A business case may also be required to support a bid, the scope of the case being proportional to the scale of investment.

2.3.3 Free issues of medical equipment and donations from companies

Some suppliers offer free issues of medical equipment to the Trust in return for a commitment to purchase consumables for use with the equipment. Such offers must be referred to the relevant procurement manager, as the total expenditure over the duration of the agreement may be high. Any equipment offered as free issue must comply with the guidance on standardisation as described in section 2.4.4. A suitable indemnity agreement must be in place before free issue equipment is delivered to the Trust. An **MIA Call-Off Indemnity Agreement** must be completed and retained for all items (see appendix 3 form 5). See section 3.8 for further guidance in regard to equipment on loan or trial.

2.3.4 Free issues of medical equipment and donations from charities

When charities, patients or their relatives wish to donate medical equipment to the Trust, the service manager must establish that the benefits to the Trust will outweigh the risks arising from its use. Such donations must be managed as with equipment procured from any other source and this should include liaison with Estates, labs, ICT, sterile services etc. as required and arrangements for asset registration/acceptance testing, training, decontamination, servicing and disposal.

The recipient must also ensure that any recurrent costs e.g. servicing and maintenance can be met within the locality/service budget. Donated equipment must also meet the requirements for standardisation and safety and performance. Donations of money, rather than equipment, would simplify the implementation of this process, as it would allow the local manager to ensure the equipment meets the medical device management process more clearly.

2.4 Selection

2.4.1. User Requirements

Users should specify the essential and desirable requirements of the equipment to be purchased. Care should be taken to avoid over-specification as equipment can become unnecessarily complex, difficult to use and expensive.

2.4.2. Technical Standards

A completed Pre Purchase Questionnaire (PPQ), must be obtained by Regional Supplies Service from each supplier under consideration. A blank copy is available in Appendix 3 (form 2). Service areas may wish to extend the PPQ to include questions specific to their speciality, e.g. compatibility with existing systems in place.

For equipment going through a centralised decontamination process sterile services have a specific extended version of the PPQ to ensure compatibility with their processes, and the service area should discuss with this with them prior to purchase of the equipment.

All devices, including **donated devices**, must comply with appropriate European Standards and be CE marked.

If it is appropriate, devices should have the desirable features as listed in paragraphs 4.31 - 4.38 of report of the Expert Working Group on Alarms on Clinical Monitors (MDA 1995) This would include secure controls (physical key/keypad lock), minimising of false alarms, clear indicator of alarm deactivation, data logging include record of setting changes)

2.4.3. Decontamination Standards

It is **essential** that the decontamination requirements for reusable medical devices under consideration for purchase are established as part of the procurement process. Input may be required from Infection Prevention Control/CDUs (Central Decontamination Units)/Pharmacy during both the preparation of the specification and at tender appraisal. Prospective suppliers will be asked to complete a detailed questionnaire on decontamination requirements when considered appropriate. This questionnaire and further guidance can be obtained from the Trust STERILE SERVICES, the Trust Decontamination of Invasive Medical Devices Policy or Decontamination of Endoscopes Policy.

2.4.4 Device Standardisation

Where equipment is used extensively throughout the Trust it is advantageous to have a high degree of standardisation. Examples would include defibrillators, NIBP (non-invasive blood pressure) monitors and infusion devices.

Standardisation will bring benefits in terms of:-

- Purchase and running costs
- User training and familiarisation
- Maintenance and support
- Risk management

Where devices not already in widespread use in the Trust are being considered, a user evaluation may be appropriate.

It should be noted that complete standardization may be undesirable as a common fault or hazard could seriously compromise the delivery of service.

Any medical device contract should be reviewed on a regular basis within the terms of the contract. Some diversification also strengthens the purchasers negotiating position with suppliers.

2.4.5 Building Services Requirements

The installation of some equipment may require advice and costings from Estate Services, who should be consulted at an early stage, with regard to any system requirements such as power supply, ventilation, plumbing and building alterations etc.

2.4.6 Specialist Liaison

It may be necessary to liaise with specialist areas for detailed technical advice and this should be considered from an early stage. This might include ICT (Information Technology), Labs for POCT (Point of Care Testing) equipment (see appendix 3 form 1b) STERILE SERVICES for decontamination issues, Community Equipment Loans Store, medical engineering, critical care scientists, medical physics etc

2.4.7 Data Security and ICT Requirements

Many medical devices can now hold patient identifiable data or be vulnerable to hacking and these risks must be included in the management of the device.

Consideration should be given to the following in consultation with ICT governance and the Information Commissioner's Office (ICO)

- 1) Adherence to standards for connectivity to the Trust network and onwards to the Internet
- 2) Adherence to the ICT technology standards
- 3) Adherence to standards for information Governance including the ICO Code of Practice
- 4) Identification of Information Assets Owners and their role
- 5) Systems which store confidential data should be recorded centrally
- 6) Decommissioning should include the removal of all confidential data
- 7) Adherence to security standards either the HSC ICT policy or ISO 27001 standard
- 8) Adherence to standards for data exchange (e.g. HL7)
- 9) A business continuity plan for critical devices if appropriate
- 10) Risk assessment if the system is cannot meet this requirement
- 11) Risk assessment for management of the device may require a Privacy Impact Assessment (PIA) to determine what risks may relate to the data held on the equipment
- 12) Clearly documented roles and responsibilities for the safe operation and support of the device

NB this applies not only to discrete computer equipment such as PCs and printers but also any medical devices which store patient data or are networked

Further information and guidance may be sought from the Trust ICT Governance department and ICO (see references below)

2.4.8 Acceptance/Performance testing

Responsibility for acceptance and/or performance testing (see section 3) should be arranged during the procurement phase. Liaison with external service areas may be necessary e.g. technical supervisors, STERILE SERVICES, ICT etc

2.4.9 Finance Services

Where procurement will require substantial monies, Finance Department should be consulted about alternative methods of funding, including leasing and Private Finance.

2.4.10 Competitive Quotations and Tenders

Suppliers must be invited to submit quotations/tenders in accordance with HSS (WS2) 1-74 [The Mini Code].

2.4.11 Maintenance Requirements and Availability of Support

Service/Maintenance arrangements are to be agreed prior to purchase even when the equipment is covered by a manufacturer's warranty. Requests for maintenance contracts should be arranged with the Estates Service Contracts department at the time of procurement.

The information they will require to set up or extend a contract can be found in form 3c – *Trust Maintenance Contract Request Form*

Differing maintenance requirements and associated costs can be a significant factor in the comparison of alternative medical devices. Availability of external maintenance support must be assessed in the light of required response times. Warranty may include a period of maintenance support or such support may be specified.

Where devices are bought to replace similar equipment already under service contract, the pre-existing contract should be updated to reflect the change in equipment

2.4.12 Training Implications

The cost and availability of initial and ongoing professional training must be established. It may be cost effective to include the provision of initial training as a requirement in the specification.

2.4.13 Total Whole Life Costs

In assessing the cost of equipment, the whole life figure should be considered, not just the initial purchase cost.

Total whole life costs may include

- Purchase
- Training
- Installation
- Consumables e.g. single use accessories, PPE, filters, laboratory costs such as QC (Quality Control) solutions
- Decontamination (if external or specialised processing required)
- Utilities e.g. electricity, water requirements
- Servicing (including frequency of service, changes in servicing requirements after prolonged time/usage)
- Upgrades including software upgrades
- Disposal requirements

Complex equipment may require additional staffing.

The Equipment Procurement checklist (Medical Devices form 1A) gives a framework for issues to consider when procuring equipment

Where a business case is required the Finance Department can assist with this process.

2.4.14 Medical Devices Supplier Representatives

When dealing with representatives of Medical Devices Suppliers, Trust staff should ensure that:

- they exercise good judgement when a decision is made to meet or request a meeting with medical device industry representatives. This is particularly important with POCT equipment, where all applications for new or replacement tests must be submitted to the POCT committee for approval. This includes requests for additional tests on currently approved analysers.
- all discussions with industry representatives must be limited to appropriate topics such as availability of equipment, range of options, performance issues, etc,
- any approach or engagement by industry representatives perceived by a member of Trust staff as inappropriate (e.g. comparisons implying product performance advantage which is not justified, disparaging comments about competing companies, disparaging comments about clinical or scientific opinions of medical or allied professions) may be reported to the Association of British Healthcare Industries via the Medical Devices manager if appropriate.
- they exercise good judgement with respect to information that they provide to industry representatives relating to the Trust, or Trust practices, including patient and commercial confidentiality, and data protection regulations
- they avoid the involvement of incumbent industry suppliers of medical equipment in the preparations for procurement competitions.

Further guidance is available in DB2006 (05) *Managing Medical Devices*, and the *ABHI CODE OF BUSINESS PRACTICE Guidelines on Interactions with Healthcare Professionals*

2.5 Manufacturer's Instructions

Purchase specifications must require that manufacturer's instructions are supplied with new medical devices, including instructions on decontamination or reprocessing. The specification will also require that the manufacturer provides the Trust with any revised instructions throughout the prospective life of the device. The default arrangement for reusable medical devices is that any such revised instructions are sent to the owners and/or holders of the equipment for appropriate dissemination to end-users, sterile services, etc.

Where instructions have been altered by the professional users, they should ensure that these are approved by the manufacturer/supplier.

2.5.1 *Equipment Procurement checklist - See appendix 3 – form 1A*

2.5.2 *POCT Procurement checklist - See appendix 3 – form 1b*

2.5.3 *Estates Maintenance Contract Request Form – form 3c*

3 Putting into Service

When a device is first delivered to the Trust it is essential that checks are carried out prior to use by the professional user.

New equipment must be formally accepted to ensure that entry into service is properly controlled. This applies equally to equipment purchased by the Trust, gifted to the Trust, on loan or on trial.

Medical devices must not be put into service without appropriate decontamination instructions and decontamination facilities being in place, and agreed with Sterile Services in advance.

The procedure will include

- Delivery checks
- Acceptance testing
- Addition to the Asset Register

Depending on the type of equipment, the various aspects of commissioning will be carried out by an appropriate combination of the manufacturer's technical representative, in-house technical staff and users.

Where practicable, all new equipment should be delivered to RSS, Estates Services/Technical Supervisor, Community Stores or directorate biomedical engineering department **by prior arrangement**, for delivery checks and acceptance testing. The location for a specific site or area can be confirmed with RSS.

3.1 Delivery Checks

The person receiving the device is responsible for;

- Checking for external damage to the package or its content.
- Checking that the correct goods have been delivered.
- Check all components and manuals are present or will be delivered separately.

3.2 Acceptance Testing

The Technical Supervisor, Estates Officer or delegated technician must ensure that Acceptance Checks including the recommended manufacturer tests are performed to ensure that the device meets the correct performance and safety standards. Records must be kept of all checks undertaken (see Acceptance Test Details form 3B).

3.3 Installation and Release of New Devices

The Technical Supervisor, Estates Officer or delegated technician is responsible for:

- Ensuring any required services are satisfactory.
- Ensuring that the device is tested for electrical safety prior to installation, if required.
- Ensuring manufacturers' guidance is available where in-house technical servicing is to be undertaken.
- Ensuring that suitable arrangements have been made for maintenance and servicing.
- Ensuring that suitable arrangements have been made for performance and or validation testing

The Department Equipment Controller should ensure that:

- Appropriate instructions for the safe and effective use of the device are available.
- Appropriate decontamination instructions and facilities are available.
- Sufficient training has been completed and records of staff trained are maintained.

3.4 Medical Devices Acceptance

A *Medical Devices & Equipment Acceptance Form* (appendix 3 – form 3b) must be completed to record the acceptance process for all new devices including those under commercial ownership. The Department Equipment Controller and the Technical Supervisor are jointly responsible for completion of the form. Typical delivery and acceptance checks are detailed in Tables 1 and 2 below

Basic guidance on delivery checks

	Delivery check	Knowledge required
Paperwork / database	<ul style="list-style-type: none"> • Is the device compatible with specification set out in the purchase order? • Have the user, repair and maintenance information, compliance and calibration certificates, as well as test results been included, where relevant? • Add device details, asset number and serial number on to device management records. • Does the device (or any component part or accessory) need decontaminating before first use? • Are the instructions for use appropriate? • Does the device require validation? • Are the Decontamination instructions appropriate? 	<ul style="list-style-type: none"> • Familiarity with: • Ordering system • Inventory system • Names and appearances of common medical devices • Medical device documentation (Instructions for Use, certificates etc) • Serial numbers and model identification codes
Visual inspection	<ul style="list-style-type: none"> • Is the outer packaging intact and undamaged? • Is there any damage apparent to the device on inspection? • Is there an appropriate: expiry date, CE marking, Notified Body number, electrical class, lot number, quantity in pack, storage information for unopened pack etc.? 	<ul style="list-style-type: none"> • Knowledge of areas to check for damage • Familiarity with: <ul style="list-style-type: none"> • the appearance of product in good condition, • common defects • Knowledge of medical devices and their use • Knowledge of electrical class symbols.
Configuration	<ul style="list-style-type: none"> • Configure the medical device in such a way as to ensure compatibility with all other equivalent medical devices in the healthcare organisation and with its clinical requirements. • Where this is a new medical device discuss with and get agreement from the responsible clinical manager/director as to how the device(s) should be configured, documenting the decision with reasons, where appropriate. 	<ul style="list-style-type: none"> • Knowledge and understanding of the medical device and its clinical application • Knowledge and understanding of the impact of configuration changes on clinical care • Knowledge of how to configure this particular device.

Table 1 (From *Managing Medical Devices*, MHRA 2015, table 5.1)

Basic guidance on safety and calibration checks

	Safety and calibration checks	Knowledge required
Functional check Note: This may require more extensive checks by specialist staff for complex or specialist device.	<ul style="list-style-type: none"> • Does the device function in line with the manufacturer's information? • Are accessories/parts included and compatible? • Do indicators and displays function correctly in line with the manufacturer's information when powered up?* • When powered up, does the device start when it should and do the dials and switches do what they say?* 	<ul style="list-style-type: none"> • For some devices, the skills required will be little more than basic training to allow the manufacturer's information to be followed. • In cases where the manufacturer's instructions specify specialist assembly or manipulation, familiarity with the functions of the device and its components and accessories is required.
Electric (basic safety)	<ul style="list-style-type: none"> • Are the mains leads, plugs and other connectors undamaged? • Are the mains plugs compatible with the sockets used in the UK (BS 1363/A)? • Mains adapters should not be used on medical devices. 	<ul style="list-style-type: none"> • Training in visual electrical safety inspection techniques.
Calibration and measurement	Where appropriate, use test device to check: <ul style="list-style-type: none"> • Accuracy of physiological measurements • Dose delivery* • Energy delivery* • Accuracy of other outputs* 	<ul style="list-style-type: none"> • Tests should be carried out by an adequately trained and appropriately qualified person.

*only for active devices

Table 2 (From *Managing Medical Devices*, MHRA 2015, table 5.2)

A *Department Inventory Record* (appendix 3 – form 4) should be completed for each medical device held in the ward or department and should include details of the type, make and model of the equipment, its serial number, contact details of the supplier and/or service agent, etc

An Indemnity form (appendix 3 – form 5) must be completed before equipment on loan or on trial goes into service (see Section 3.8)

3.4.1 Medical Devices Registration/Acceptance Form

see appendix 3 – form 3 parts A&B

3.4.2 Department Inventory Record

see appendix 3 – form 4

3.5 Equipment Registration on the Asset Register

All new equipment should be registered with Estates Services by contacting the Asset management helpdesk and supplying the information requested on the *Medical Devices Registration/Acceptance Form (appendix 3 Form 3)*. Estate Services will assign a unique asset identification number which will remain with the device whilst in use within the Trust. Where practicable, an asset label will be affixed to the equipment itself. Asset labels (of varying sizes) will be supplied by Estates Services when the equipment is first registered and replacements can be provided on request

3.6 Storage of New Devices

Department Equipment Controllers, Equipment Assistants, Community Equipment Loan Stores staff are to take care when storing new devices as inappropriate storage of items can affect their subsequent safe use. Manufacturer's information and instructions both on storage conditions and shelf life should be followed.

In particular they should consider the following:

- Avoid storing fragile devices too far off the ground.
- Separate devices needing decontamination and repair from devices ready to use.
- Storage conditions are suitable for the device.
- Devices and consumables are used in good rotation to avoid being stored for too long or the shelf life of batteries and sterile products being exceeded.
- Battery operated equipment should be kept on charge when not in use, as indicated by the manufacturer's instructions. If it is not possible to have all equipment on charge at any one time, there should be a system of rotation in place to ensure adequate charging

3.7 Prescription of Medical Devices

Directorates are responsible for making sure that prescribing of medical devices is performed by staff with appropriate professional qualifications and suitable experience. The prescription is the responsibility of the prescribing professional. *Directorates* must have procedures to ensure that suitably qualified and experienced staff undertake the prescription of different types of medical devices.

All devices prescribed must be appropriate for the individual patient's use

When a medical device is prescribed for use by patients in the Community, staff should also take into account the points in section 3.9 *Medical Devices on Loan to Patients*

3.8 Medical Devices on Trial or on Loan to Trust (not to Patients)

The Trust must satisfy itself that all medical devices used on its premises, including devices on temporary loan or trial, are safe, suitable for their intended purposes and that arrangements for their use are satisfactory.

This guidance below does not apply to short term loans between adjacent departments or areas, or other public bodies external to the Trust. In all instances however there is a requirement for staff borrowing the equipment to know how to use it safely, maintain it correctly and decontaminate it appropriately.

The Consultant or the manager of the relevant Service Speciality/Area **must** agree to a medical device being on loan or accepted for trial, and that it is suitable for its intended purpose. Prior to acceptance of the equipment it is also essential that the supplier has appropriate valid public liability insurance.

The service area should check if the supplier already has an agreement in place with the Trust or one of the national Indemnity register schemes in England, Wales or Scotland

England	www.gov.uk/government/publications/master-indemnity-agreement-mia
Scotland	www.hfs.scot.nhs.uk/online-services/master-indemnity-agreement
Wales	www.whs.wales.nhs.uk/supply/masterindemnity

If there is an existing indemnity arrangement check that their public liability insurance is valid for Northern Ireland and complete the **MIA Call-Off Agreement** (appendix 3 FORM 5.2)

which includes a reference to their national master indemnity register number or the original Trust indemnity Form that they completed

If there is no pre-existing arrangement then the supplier must supply a copy of their valid public liability insurance and complete the **MIA Call-Off Agreement** (appendix 3 FORM 5.2). The supplier should also be advised to complete an **Overarching Master Indemnity Agreement** (appendix 3 FORM 5.1).and they should then submit this to the Department of Health

See section 3.9 for Loan of Equipment to Patients

The Consultant or the manager of the Service Speciality/Area must:

- Ensure that the supplier's National Indemnity Register entry has been checked or that the supplier has valid public liability insurance
- Ensure that **MIA Call-Off Agreement** (appendix 3 – form 5.2) has been completed prior to the device going into service, Copies of this should be retained by the service area and the supplier
- Instruct the supplier to contact the appropriate Technical Supervisor at least 2 days prior to delivery.
- Be satisfied that proper arrangements have been made for its use including training of staff, decontamination and servicing arrangements as required, following the Trust's guidance on the delivery of new devices and training requirements.
- Carry out an assessment of the financial implications of using this equipment, both short- and long term.
- Ensure that there is a decontamination service in place prior to its acceptance if appropriate.
- Ensure that there is an adequate traceability system in place if appropriate (Form 3A, asset acceptance/registration).
- Ensure that there is acceptance checking of the loaned equipment (see Acceptance Testing section 3.2 - see Acceptance Test Details form 3B)
- Ensure that manufacturer's instructions have been provided.
- Ensure that there is periodic checking of loaned equipment for functionality and safety and repair in accordance with manufacturer's instructions, whether by the Trust, supplier/manufacturer or a third party.
- Ensure that there is a clear definition of responsibilities for the maintenance, repair and regular safety checks of loaned equipment (including identifying the person(s) responsible for initiating the testing of the equipment and those responsible for performing the testing).
- Ensure that there are adequate instructions regarding decontamination (cleaning/disinfection/sterilization) of re-usable equipment and availability of appropriate equipment/facilities to carry out reprocessing.
- Establish a protocol by which the service area can identify medical devices on loan and ensure appropriate withdrawal or return of unwanted or obsolete loaned equipment.

The Technical Supervisor must;

- Ensure that the device complies with appropriate European Standards and is CE marked, and check that it is electrically safe, where appropriate
- Ensure that any environmental, safety or installation problems are discussed with the appropriate persons, including Estate Services.
- Identify loan period and inform the supplier of the return of device at the end of the loan period or request renewal of the period.

Where on-loan equipment is being transferred between different departments within the Trust and further decontamination is required, a copy of the appropriate manufacturer's

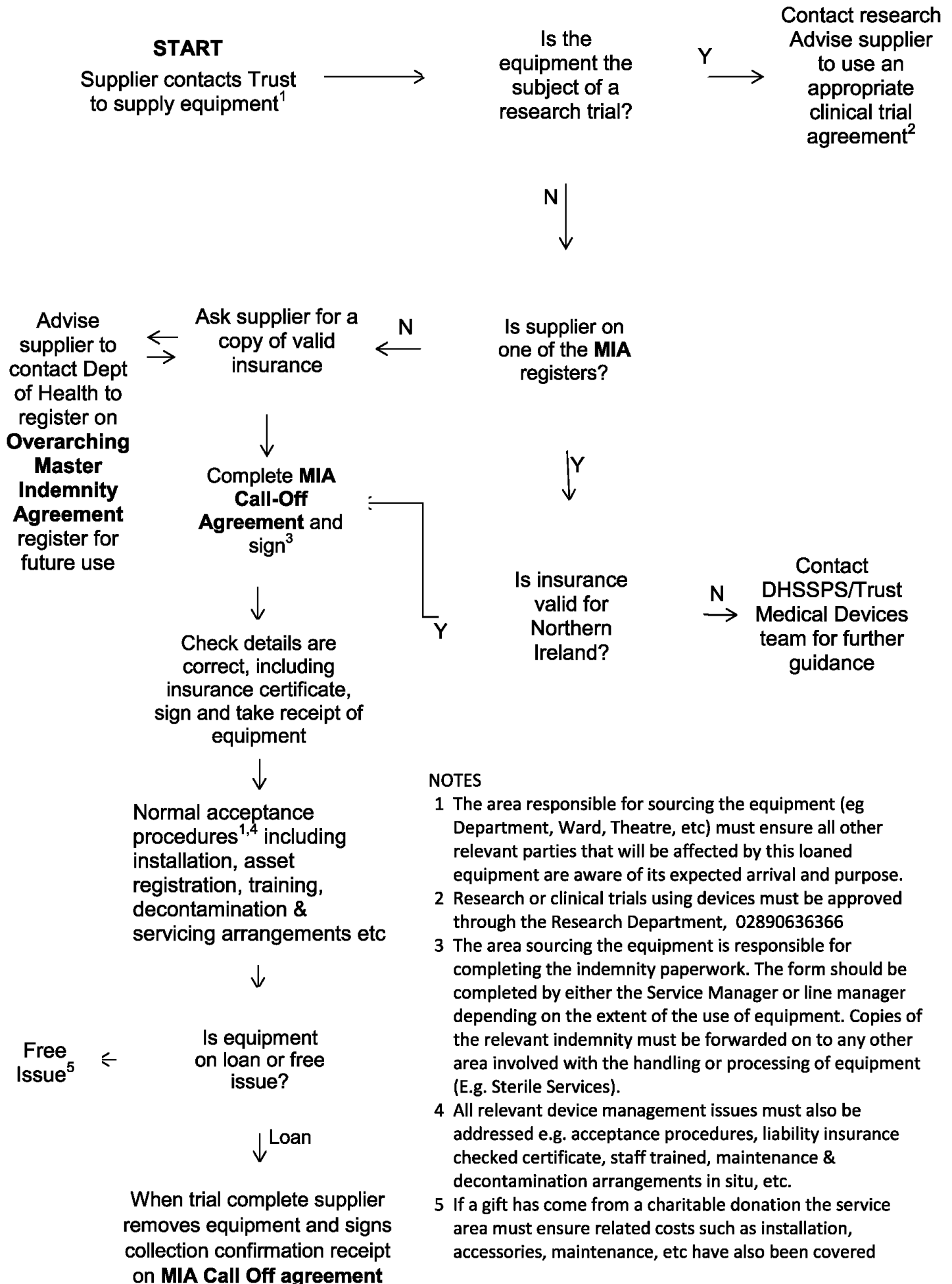
instructions, completed decontamination certificate (Form 10b) and/or instrumentation lists must be available to all relevant users

3.8.1 *Trial/Loan Indemnity Forms*

See appendix 3 – part 5

- **Guidance Notes on Indemnity, can be printed off as a quick reference guide**
- **FORM 5a - Overarching Master Indemnity Agreement**
- **FORM 5b - MIA Call-Off Agreement**

Flowchart for Indemnity Process



NOTES

- 1 The area responsible for sourcing the equipment (eg Department, Ward, Theatre, etc) must ensure all other relevant parties that will be affected by this loaned equipment are aware of its expected arrival and purpose.
- 2 Research or clinical trials using devices must be approved through the Research Department, 02890636366
- 3 The area sourcing the equipment is responsible for completing the indemnity paperwork. The form should be completed by either the Service Manager or line manager depending on the extent of the use of equipment. Copies of the relevant indemnity must be forwarded on to any other area involved with the handling or processing of equipment (E.g. Sterile Services).
- 4 All relevant device management issues must also be addressed e.g. acceptance procedures, liability insurance checked certificate, staff trained, maintenance & decontamination arrangements in situ, etc.
- 5 If a gift has come from a charitable donation the service area must ensure related costs such as installation, accessories, maintenance, etc have also been covered

3.9 Medical Devices on Loan to Patients

Departments issuing patients with devices for use both within the Trust and outside should ensure that

- Patients, clients, carers or relatives are trained in the safe and effective use of the medical device (checklist 3.9.2 below). The training given should be recorded in the patient's notes and on the loan record (appendix 3 – form 6).
- Training should also include the need for safe care and return of the equipment, especially in the case of expensive or scarce equipment. The specific process required will depend on the service area, the equipment involved, their clientele, etc
- IFUs (Instructions for Use) should be supplied to patient, clients, carers or relatives in addition to training (see 4.5.3)
- IFUs (Instructions for Use) given to patients or carers must be evaluated for suitability by the prescribing professional in consultation with the supplier if required (see also section 4.5 below).
- A risk assessment may be required and this might come from the service area issuing the equipment or the department supplying the equipment, eg following a safety alert on the risk of fires on mattress provided for use at home, HALO identify the mattresses at risk and the district nurses complete the appropriate risk assessment.
- Patients, clients, carers or relatives are made aware of the administrative and technical support and relevant contact numbers including contact in case of problems, and details for return of equipment
- Medical devices on loan should be recorded on the Trust Asset Management system or a suitable local loan record (appendix 3 – form 6). The details recorded should include date of loan, date of expected and actual return, names of persons making loan and to whom the equipment has been lent, identifying asset/serial number of item, training/instruction given, etc
- Medical devices are collected after use by the relevant department or organised through the commercial owner if required.
- All end-users are aware of the need to take care of equipment whilst on loan and that it should be returned as promptly and in as good condition as possible for future use

The issues in 3.9 above are detailed in the following checklist 3.9.2

3.9.1 Record of Equipment on Loan to Patient/Client/Carer (appendix 3 – form 6)

3.9.2 Checklist for Patients Discharged with a Medical Device

General Considerations

- Is the device suitable for home use (have the following been considered if appropriate, robustness, back-up systems, alarms, modifications needed, patient/client care and instructions)?
- Has the person responsible for use of the device been identified, i.e. is it patient/client and/or carer?
- Has a risk assessment been completed, if required?

Patient/Client/Carer Instructions

- Does the patient/client/carers know why the device is required?
- Does the patient/client/carers know the name of the device?
- Does the patient/client/carers know how to set up the device in the home?
- Has the patient/client/carers been trained in the use and functions of the device?
- Has the patient/client/carers been trained in how to deal with fail-safe features, e.g. alarms?
- Has the patient/client/carers been trained in the care of the device?
- Does the patient/client/carers require accessories? If so, does the patient/carers know where to obtain these and how often?
- Is maintenance required? If so, is the patient/client/carers aware when this is required, and the requirement for access to the equipment?
- Does the patient/client/carers have a point of contact in the Trust for any routine queries?
- If relevant, does the patient/client/carers have a contact point in case of emergency?

Return

- Does the patient/client/carers know where to return the device once treatment is complete, to whom and at what time?

3.10 Modifications

*Medical Devices should **not be modified**, or used for purposes not intended by the manufacturer.* MDA 2010/01

Modification may have an impact on the former conformity assessment of the medical device, primarily concerning safety, reliability and intended use. If so, the CE-marking is no longer valid and the product liability is seriously affected: both are based on the state of the Medical Device when it was put into service for the first time. If the user substantially modifies a device, they become the **Manufacturer** of a new device, according to the Medical Devices Regulations, and they must take legal and regulatory requirements into account.

Such a modified device can no longer be used under the original CE marking. The modified device will still have to comply with the prevailing regulations, but a new CE marking is not needed, if the modification is for internal Trust use (i.e. within the same legal entity) only. The original Manufacturer's responsibility and liability can be limited and the user or modifier may be exposed to legal action, if the device is involved in an adverse event.

If a device is used outside the original intended purpose, as indicated by the Manufacturer, the user must be aware that the device has not been validated for this off-label use by the original Manufacturer. Again, the responsibility and liability of the original Manufacturer are limited and the user will be exposed to legal action, if an adverse event occurs.

For any modification of the medical device the status of the documentation and instructions for use needs to be verified for compliance with the new hardware/software configuration, by the person responsible for the modification. That person should also fulfil the requirements imposed on a Manufacturer of medical devices, such as performing a risk analysis and, if needed, undertake risk management.

Where a healthcare professional judges that there is no alternative to off-label use or modification of an existing medical or non-medical device they should:

- Consider the ethical and legal implications of the intended use
- Carry out and document a full risk assessment
- Ensure the patient is fully informed through the consent period and the situation is documented in the patient's notes

Cannibalising (re-use of parts from redundant) medical devices/equipment is not a recommended acquisition option

3.11 In-house Medical Device Manufacture

Those wishing to manufacture devices in-house should refer to the specific policy on this in conjunction with the Research department or Medical Physics, and liaise with them for further advice and guidance. In the latter case such equipment needs to be submitted to, and approved by the Medical Devices Advisory Committee

3.12 Research/Clinical Studies and Medical Devices

Even if only being used in a research trial, the same principles apply to medical devices in studies as with all medical devices, namely that;

- The device should be appropriate for the task intended (see procurement section 2.2)

- There should be a fully documented risk assessment carried out
- the end-users should be trained in the operation of the device (see training section 4 and training checklist/records - appendix 3 forms 7-9)
- that safety for the user and patient/client is paramount

Further details on the specific use of medical devices for trials/studies/research are detailed in the Trust Research guidelines, *How to submit a clinical investigation application for a non CE marked device or a CE marked device for a new purpose* (BHSCT/RG/SOP 017) and on the NHS Health Research authority webpage, *Ethical Review of Investigations of Medical Devices*

4 Training

4.1 Generic Training

All clinical and technical staff should be trained in the generic care and attention of all equipment including medical devices and an awareness of related issues. This training will be provided by the Trust at *Medical Devices Awareness* sessions and should be attended at induction or soon after and then refreshed at three yearly intervals. These sessions may be booked through the HRPTS system but in-house sessions can be delivered to specific areas or services by arrangement

DECs and Managers must undertake the *Medical Devices for Managers & DECs* training session which includes and expands on the material in the *Medical Device Awareness* session and also includes risk assessment and implementation of the Medical Devices Policy and Procedures & Guidelines

4.2 Specific Training

Directorates must ensure that professional users are trained in the safe operation of all medical devices that they use. Where relevant the professional user should:

- Be able to choose the appropriate device for the intended purpose
- Be made familiar with the operation of any medical device they are required to use.
- Be aware of differences between models of a given device, if appropriate.
- Be able to assemble the device following cleaning and fit appropriate accessories.
- Be able to set the controls or parameters correctly.
- Be able to recognise malfunctions.
- Be able to correct malfunctions if appropriate, or withdraw the device from service and contact the appropriate person.
- Be able to connect the device to a patient effectively and safely, causing minimum discomfort.
- If appropriate, be able to show the patient/client how to use the device,.
- Know how to clean a device and organise its decontamination if required.
- Be familiar with adverse incident reporting requirements.

This is fully detailed in the **Equipment Training & Familiarisation Schedule** (section 4.2.1)
See appendix 3 –form 7 - training schedule

Prior to training commencing, the training programme should be assessed by the Technical Supervisor and/or Department Equipment Controller to ensure it is sufficient and suitable.

No new medical equipment should be allowed to enter service until potential users have had adequate training in its use, user servicing and emergency action in the event of malfunction.

When a new device is introduced initial training requirements must be identified and appropriate training made available as part of the commissioning process. This can be provided by the supplier or by experienced in-house staff as appropriate. It is recommended that for new devices coming into service that training is provided by the supplier/manufacturer are part of the provision of the equipment. Ongoing training must be provided over the lifetime of the device and this can be provided by the supplier or by in-house staff as appropriate.

Records must be kept by the Directorate of all training on the Department Training record (appendix 3 – form 8) and users should sign statements to the effect that they have received

instruction on the safe use of the item in question, and a statement of competency if required. Training records should also be kept by each individual of the equipment they have been trained on, on the form provided (appendix 3 – form 9). Where an area already has suitable records of training provided these may be retained and do not have to be transcribed onto the new training records in these guidelines. A copy of the training programme for each type of equipment should be retained in the service area with the relevant training records. Frequency of refresher training should be identified and provided in conjunction with the supplier's/manufacturer's recommendations.

Appropriate information from the manufacturers' Instructions should be disseminated and made available to all users. Users should also be notified when instructions are updated. A copy of the instructions for each device should be held by each user department.

Instruction manuals must be amended to take account of subsequent updates or revisions and users alerted where appropriate.

All health care professionals are accountable for ensuring they use Medical Devices safely in line with relevant training, Instructions, legislation and guidance.

4.2.1 Equipment Training & Familiarisation Schedule

See appendix 3 – form 7

4.2.2 Medical Device Training Record – department record

See appendix 3 – form 8

4.2.3 Medical Device Training Record – personal record

See appendix 3 – form 9

4.3 Statement of Practice

Professional users have a responsibility to seek appropriate training before using any medical device or equipment.

The Trust expects all staff to adhere to the following principles before using any medical device:

- Do not use equipment unless you have been trained to do so.
- Always visually check the equipment for signs of damage or incorrect settings before each use.
- If the equipment requires disposables, ensure they are appropriate for the device and for its current settings.
- Do not be afraid to ask advice of senior staff, medical technical officers, biomedical or clinical engineering, medical physics, the Instrument Curators Office, Estate Services, Community Loans stores or experienced colleagues in other Directorates.

Where external experts/representatives are providing training they should be competent to train in the use of the equipment and address the above issues, as detailed in the **Equipment Training & Familiarisation Schedule** (See appendix 3 – training schedule form 7).

Where training is provided by a supplier, they should provide the Directorate / Trust with

- A copy of the training materials used in any training programmes (this may need to be technically inspected by specialist areas such Labs or medical engineering)
- A list of staff who attended this training.

4.4 Defined Training Requirements

In conjunction with medical physics medical devices will be classified into high, medium or low risk categories depending on the risk to patients that may arise due to incorrect or inappropriate use.

The following are examples for illustration only:-

Low risk – Stethoscope, patella hammer

Medium risk - Pulse oximeter, blood pressure cuff

High risk – defibrillator, Infusion pump

The overall risk would take into account both the severity and likelihood of any detrimental incident occurring.

Training should be appropriate to the risk category of the equipment

4.4.1 General Use – Low to Medium Risk Medical Devices

This applies to all equipment that is not listed either in the specialist or high risk categories. It is acceptable for training on the use and maintenance of equipment to be part of the induction of staff to their clinical area and carried out locally.

Training can then be given on an individual basis, depending on their experience and expertise.

4.4.2 General Use – High Risk Medical Devices

The following are examples of devices that are generally considered high risk:-

- Infusion Devices
- Syringe Drivers
- PCAS (Patient Controlled Analgesia system)
- Resuscitation Equipment
- Defibrillators
- Blood Gas Analysers
- Epidural Infusion device
- Electronic Blood Glucose monitors
- Surgical instrumentation

This list should not be considered as definitive or exhaustive.

Staff using high risk devices must attend specific training that will require not only records of training attended but also confirmation of individual competence, through recorded supervised practice.

4.4.3 Specialist Areas

This applies to all the specialist areas where there is a concentration of complex Medical Devices, e.g. Theatres/Recovery/HDU, Critical Care Units, Radiology, Accident/Emergency, and any other area where specialist equipment is routinely used.

In these areas there is highly specialised equipment, e.g. ventilators, incubators, anaesthetic machines and there should be evidence of training undertaken that includes the training material/user manual used and proof of assessment based competency.

Usage of this type of equipment outside of the specialist area should be kept to the absolute minimum. Where it is necessary, for clinical reasons, to use the equipment in a general clinical area, then only a person competent to do so can operate it.

4.5 Instructions for Use

Good clear instructions are essential for safe and effective use of equipment and it is important that these should be available to both professional users and end-users

4.5.1 instructions for professional users

All professional users should have access to up to date instructions for the medical devices that they are expected to use in their practice. During the procurement process there should be provision of instructions by the manufacturer/supplier and these should be updated when there are any changes made.

Provision of instructions alone is not a substitute for adequate training

4.5.2 Updates of instructions

When manufacturers update their information there is the risk that this may not be conveyed to the relevant clinical areas. Any specifications created for equipment procurement should contain a provision for the manufacturer/supplier to pass on any updated instructions/information for the lifetime of the contract/equipment

The Department Equipment Controller should make provision for the retention of equipment instructions, manuals etc and keeping track of all sets of instructions they hold or have issued to users. They should keep a record of when existing instructions have been replaced with revised versions and record the changed content and provision of the relevant updated training. Obsolete copies should be marked as such and removed from use.

These changes can be recorded in the relevant equipment records in the ward/department's Management of Medical Devices folder

4.5.3 instructions for end users

A failure to pass on to the end user the manufacturer's original instructions may compromise the end user's ability to use the device safely, and may render the provider open to legal liability under:

- The Consumer Protection Act 1987 (in the case of a medical device)
- The General Product Safety Regulations 2005 (in the case of a consumer product not covered by other specific legislation)
- The common law of negligence.

Some users or carers with particular disabilities or medical conditions may need additional instructions or training. For example, people who are visually impaired may not be able to easily read some forms of written information.

Instructions may need to be written locally to cover whole systems where devices are used together with other equipment such as connecting a blood analyser to a computer to permit automatic updating of patient records.

The responsible service area may also need to supply its own information to explain any additional administrative arrangements e.g. contact details for maintenance, consumables or spare parts

If areas draft their own instructions to supplement the manufacturer's instructions, they should consider obtaining feedback on their accuracy and confirmation of suitability from the manufacturer before issue.

The operating instructions or instructions for use give important information for the proper use of the medical device, for example:

- Definition of the intended use of the equipment
- Explanation of the user's controls and display
- Safety instructions and warnings for the user
- Instructions how to deal with inherent residual risks
- Avoidance of misuse
- Decontamination instructions
- List of accessories and consumables validated by the manufacturer
- Requirements for safety inspections of the equipment
- Requirements for (planned) maintenance

Ignoring or not fully recognising or understanding the instructions for use may result in:

- Decreased efficiency of operation
- False treatment/intervention or diagnosis
- Detrimental effects on the health of the patient, the user or other persons
- Deterioration of the equipment

Recommendations

The user should check that the appropriate instructions for use as well as the technical documentation are supplied together with the medical device in the required language. The instructions for use should be directly accessible for the operators of the medical device at any time.

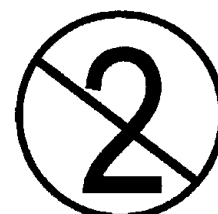
Provision of instructions alone is not a substitute for adequate training

5 Decontamination

Medical devices and equipment which are used on more than one patient may act as vehicles for the transmission of infection between patients. All such devices must therefore be adequately decontaminated between each patient use. A summary of responsibilities and guidelines are provided below and in figure 2 but this topic is covered more fully in the Trust's Policies and Procedures on *Decontamination of Reusable Invasive Medical Devices* and *Decontamination of Endoscopes, TOE probes and related equipment*

5.1. Management Responsibilities

- All reusable medical equipment which is used for more than one patient must be decontaminated between patients to ensure that there is no risk of transmitting infection by this route.
- Medical devices identified as single-use **must not** be re-used. The Single Use symbol may be present on the equipment or only on the packaging.
- It is essential that, wherever possible, reusable items should be reprocessed in an accredited centralised Sterile Services unit (CDU (Central Decontamination Unit) or EDU (Endoscopy Decontamination Unit)).
- The use of Bench Top Sterilizers is to be kept to a minimum with the preferred option for decontamination being the use of an accredited CDU. Where Bench Top sterilizers must be used in the interim, this must be recorded in the appropriate Service Area Risk Register.
- The decontamination procedures must be in accordance with the recommendations contained in the UK Department of Health documents.
- Where applicable, items of re-usable medical devices or equipment will have a record kept of the decontamination processes used and a list of the patients on whom the item was used.
- A written procedure stating the correct decontamination process for each item of medical equipment and device must be held in the department in which it is used.
- Each organisation/department must have a nominated person who must assume overall responsibility for ensuring compliance with the above requirements.
- Where applicable, equipment must be adequately decontaminated prior to servicing, inspection or repair as outlined in Section 6.5.2 and Form 10a, and a completed Decontamination status certificate (Form 10b) attached.
- Staff who are responsible for the decontamination of medical devices and equipment must have training and be deemed competent in the relevant decontamination procedures.
- Each Head of Department should ensure that decontamination of all items of equipment in their department is carried out in accordance with manufacturer's guidance and infection prevention control requirements.
- Before purchase of any equipment, it is essential to ensure that the equipment may be adequately decontaminated. New items of equipment should be compatible with Sterile Services' processes and comply with both the manufacturer's recommendations on decontamination and Trust infection prevention control requirements.
- Equipment used for sterilization or disinfection must be commissioned on installation, regularly serviced, maintained and tested in accordance with the manufacturer's instructions and current advice from the Department of Health. A written record must be kept by the Head of Department. The equipment performance must be monitored to ensure that accepted standards of safety are achieved and monitored.



- Service areas must be aware that some reusable devices/equipment may have a limited number of uses. In these instances they must ensure that there are appropriate arrangements in place to control the number of uses. This may be arranged in conjunction with the manufacturer/supplier and/or the relevant CDU/EDU

Refer to the Trust's Infection Prevention Control Manual and the Trust's Policies and Procedures on *Decontamination of Reusable Invasive Medical Devices* and *Decontamination of Endoscopes, TOE probes and related equipment* for further guidance on decontamination.

5.2. Specific Guidelines for Decontamination of Invasive Medical Devices

Decontamination procedures for specific equipment should follow the recommendations in the manufacturer's instructions, and these instructions must be supplied by the supplier/manufacturer as part of the procurement process

5.3. Handling of Invasive Medical Devices on Loan from Another Organisation

Situations may arise necessitating the loan of medical devices from external organisations.

This practice has the potential to increase the risks associated with the decontamination of instrumentation with regard to the use of appropriate processes and ensuring adequate traceability. Implementation of additional controls is therefore necessary to ensure safe use.

Objectives

- To ensure patient and staff safety.
- To ensure safe and effective decontamination of on loan instrumentation.
- To ensure safe use of on loan instrumentation.
- To ensure adequate traceability records are maintained.

Procedure

1. All instrumentation/medical devices on trial or on loan to the Trust must be subjected to an acceptance and indemnity procedures in line with Trust policy (see sections 3.2 & 3.8). Departments borrowing, trialling or renting invasive instrumentation which require decontamination must also include the following steps as part of this process.
 - Confirm that the instrumentation is suitable for intended use in line with manufacturer's instructions.
 - Confirm current decontamination status (instrumentation whether sterile or non sterile on arrival in the Trust, should be checked and sent to the CDU/EDU before use.
 - Confirm availability of full decontamination instructions for both the instrumentation and if applicable carriage boxes.
 - Ensure on-loan instrumentation conforms with decontamination guidelines available from the providing CDU/EDU, indicating the parameters used for local decontamination processes.
 - Check and confirm the presence of a comprehensive list of contents.
 - Ensure completion of all information together with manufacturer's instructions is forwarded to the CDU/EDU
 - Instrumentation planned for long term loan must have the above information forwarded to the CDU/EDU with the normal documentation required for addition of new equipment to the traceability system. This will allow future episodes of decontamination to be completed routinely by the CDU/EDU

2. Medical devices designated single use must not be reprocessed.
3. On loan instrumentation must be effectively decontaminated both prior to and after use in a CDU/EDU in accordance with the manufacturer's instructions.
4. Sterile Services must ensure that a comprehensive traceability system is in place and maintained
5. Sterile Services must have timely access to all necessary information and equipment to ensure its availability for patient use.
6. Clinical staff must ensure contact with the CDU to allow necessary arrangements to be put in place, and that sufficient time is provided to allow necessary checks and processes for the desired date of use.
7. It is the borrowing department's responsibility to check 'on loan' instrumentation and complete all necessary documentation, ensuring its inclusion prior to arranging transportation to the CDU/EDU. This may be arranged in conjunction with the CDU/EDU
8. If deemed necessary a representative for the manufacturing company must be available to give guidance on dismantling procedures or any other handling issues which may be identified by the CDU/EDU.
9. Delicate instrumentation must be protected from physical damage during the wash process by a suitable carriage box or wash basket
10. Ensure that instrumentation is positioned within suitable carriage boxes or wash baskets which will facilitate decontamination in a washer disinfectant by allowing the free circulation of water
11. Copies of on-loan documentation must be retained by the CDU/EDU indefinitely

5.3.1 Decontamination certificate for repairs/servicing/investigation/disposal
See appendix 3 – form 10

Medical and Nursing Equipment Cleaning Guide

RISK ASSESSMENT

See Manufacturer's Instructions and Risk Assess Items

LOW RISK EQUIPMENT

- * In contact with healthy skin
- * Not in contact with patient

INTERMEDIATE RISK EQUIPMENT

- * In contact with mucous membranes
- * Contaminated with particularly virulent or readily transmissible organisms
- * Prior to use on immunocompromised patients

HIGH RISK EQUIPMENT

- * In close contact with a break in the skin or mucous membranes
- * For introduction into sterile body parts

LOW Detergent Wipes		HIGH Sterilisation
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COMMON ITEMS

CLEANING OF EQUIPMENT USED FOR PATIENT WITH NO KNOWN INFECTION / COLONISATION

- * Detergent wipes for daily cleaning of nursing / medical equipment

BP CUFFS/TOURNIQUETS

- * Where possible, use single patient use (disposable) cuffs and tourniquets.
- * Where there is known infection, single patient use (disposable) cuffs and tourniquets must be used.
- * Where there is no known infection, clean after each use with either alcohol or detergent wipes or use disposables.

SINGLE PATIENT USE ITEMS

- * Clean after each use with detergent wipes and dispose of on discharge
- * If contaminated with blood or body fluids during use - dispose.

SHARED USE ITEMS e.g.

- Wheelchairs
- Hoists
- Zimmers
- Weighing Chairs
- IV Stands
- BP Monitors
- * Clean daily and between patients

CLEANING OF EQUIPMENT USED WITH PATIENTS WHO HAVE:

- * Known resistant bacteria eg MRSA
- * Viral infection eg Norovirus
- * Spore producing conditions eg C.difficile
- * **Clean all equipment with Actichlor Plus* 1,000ppm after each use**
- * Note manufacturer's instructions*

COMMODOES/RAISED TOILET SEATS

- * All commodes must be thoroughly cleaned once daily and after every use with Actichlor plus 1.000ppm.
- * Raised Toilet seats must be thoroughly cleaned once daily with Actichlor plus 1.000ppm and cleaned as required throughout the day.

BEDS

- * All beds (upper frame, mattress and pillows) must be cleaned with Actichlor Plus 1.000ppm on patient discharge
- * Long term patient - beds should have weekly clean with Actichlor Plus 1,000ppm.

* Single Use = use once and discard / Single Patient Use = use for one patient only

NB - Use Actichlor Plus 10,000ppm for blood spills

Figure 2 - Equipment Cleaning Guide

6. Maintenance

Systems must be in place to co-ordinate and manage the maintenance and repair of all devices. Accessible records should be kept on these.

The Service speciality/area manager must have systems in place to ensure that staff are made aware of any Safety Alert notices issued relating to Medical Devices used within the Directorate.

To ensure equipment remains safe and serviceable, the maintenance system should be divided into three tiers

- **User servicing** (user care and maintenance)
- **Scheduled Servicing** (PPM - planned preventative maintenance)
- **Unscheduled Servicing** (emergency repairs)

Estates Services/Technical Supervisors can advise as to servicing requirements and service contracts in place. Requests for maintenance contracts should be arranged with estates at the time of procurement, even when the equipment is covered by a manufacturer's warranty. The information required can be found in form 3c – *Trust Maintenance Contract Request Form*

Records must be kept of servicing history and they should be accessible to users of the equipment and those responsible for maintenance/servicing (see section 1.5 above). These records should contain details of

- Inspections and routine servicing
- Repairs
- Modifications including software or hardware upgrades
- Faults reported

6.1 User Servicing (Routine User Maintenance)

Routine maintenance by the user ensures that the device continues to function correctly. It entails regular inspection and care, as recommended in the manufacturer's user information. This should clearly show the routine tasks and how they should be carried out. These will include:

- Regular cleaning
- Checking that the item is working correctly before use
- Specific daily/weekly checks (to be undertaken by the Department Equipment Assistant or designated equivalent e.g. community stores personnel, patient, carer or relative)
- Noting when the item has stopped working properly or when obvious damage has occurred, and then discontinuing use
- Contacting the relevant servicing organisation through the Estates Department defect/repair helpdesk.

Minor changes that do not affect the safe working of the device can be recorded for later attention during preventive maintenance sessions.

User servicing must be limited to that which is within the knowledge and capability of the person using the equipment. Users may need to be trained to carry out routine maintenance. For example, they may require training on how to remove, change and insert batteries correctly in line with the manufacturer's instructions. They may also need to be warned about the dangers of substituting different battery types.

Although User Servicing will be principally the responsibility of the Equipment Assistant, all clinical staff using equipment should be aware of the necessity to check equipment before use, use equipment correctly and notify Estates/technical supervisor if a fault is found

6.2 Scheduled Servicing (PPM - planned preventative maintenance)

The Department Equipment Controller should ensure that for any new or existing equipment in their department that a maintenance regime is in place. They should liaise with the Estates Department to ensure the appropriate maintenance contract has been raised and regular monitoring and servicing is carried out as per the manufacturer's recommendations.

Planned preventative maintenance should follow manufacturer's guidance and DHSS requirements. Planned preventative maintenance may be undertaken either by in-house technical staff or suitably qualified contractors. The Department Equipment Controller should arrange convenient times for servicing in liaison with the service agents or Estates Department/Technical Supervisors.

The Technical Supervisor/s will keep these arrangements under review in light of contractor performance, availability of suitably qualified in house technical staff, comparative costs and risk management considerations.

When equipment is decommissioned and removed from the Trust (by disposal or transfer) Estates should be informed to update their asset management system and remove that equipment from any servicing or maintenance contracts

6.3 Unscheduled Servicing (emergency repairs/Breakdown Servicing)

Arrangements must be in place to deal with breakdowns in a timely fashion either through immediate repair or initial substitution of the device followed by repair. Where sufficient resources are available, breakdowns of the more common devices can often be dealt with in the first instance by substituting an equivalent device either held in the Department or the Directorate, elsewhere in the Trust or as a spare by the Estate Services, Technical Supervisor, or Community Stores. In other cases, maintenance contracts will require the contractor to deliver a loan device within a specified time.

6.4 Reporting Breakdowns

6.4.1 Where Estate Services Arrange Maintenance & Repairs

Where a directorate does not have easy access to a technical Supervisor or biomedical engineering service, repairs should be arranged through the Estates service to ensure that repairs are made in line with the service contract with the relevant service agent.

A record should be made of the service details on the inventory record of the equipment in the service history section of the Management of Medical Devices folder

6.4.2 Where Directorate Staff Arrange Maintenance & Repairs

Where a directorate has access to a technical Supervisor or Biomedical Engineering Service, repairs should be arranged directly with them

It is the responsibility of the Department Equipment Controller to ensure that a record is kept of any servicing required and carried out. The service details may be kept locally on the inventory record of the equipment (in the service history section of the Management of Medical Devices folder) or may be held by the department providing the servicing

6.5 Trust in-house Service/Technical Departments

Depending on their location and prior arrangements staff can call upon technical advice, support and servicing from various Trust service/technical departments including

- Medical Physics – Clinical Engineering
- Medical Physics – Radiotherapy Engineering
- Estates – Medical Engineering
- Estates – Decontamination Engineering
- Cardiology Bioengineering
- Renal Engineering
- Rehabilitation Engineering

6.6 Decontamination before Servicing & Repair

Medical devices to be inspected, serviced or repaired should carry a minimal risk of Infection. Guidance on the need for decontamination of devices prior to inspection, service or repair has been issued by the Department of Health in PEL (96)30.

Service areas should have procedures in place to minimise the time between contamination and decontamination to make it easier to clean equipment effectively

Decontamination procedures used should follow the recommendations in the manufacturer's instructions, and where necessary be recorded on the Declaration of Contamination Status (Decontamination Clearance) Certificate (*See appendix 3 – form 10*)

6.6.1 Routine Decontamination Procedures

The service area needs to ensure that there is a decontamination service available to process devices/equipment as required. This may be completed locally, centrally (CDU/EDU) or external to the Trust. Preference should be to have decontamination services completed within an accredited CDU/EDU where possible.

6.6.2 Decontamination for Servicing or Repair

It is the responsibility of the professional user to ensure that any device which requires servicing or repair is decontaminated prior to transfer to the service agent. A decontamination certificate (appendix 3 – form 10) must be completed and accompany the equipment. If it is not possible to decontaminate an item this should be stated on the decontamination certificate, and the service agent be made aware of this.

6.7 Devices Returned to Manufacturers

The service area is responsible for ensuring that equipment is returned to the manufacturer for repair.

- Where appropriate Estates must be made aware of the transfer, if the repair or servicing is made under contract
- Where equipment is capable of storing information that may identify a patient (eg monitors or imaging equipment) ensure that the equipment company or third-party repair agents are aware of this and that they must safeguard the confidentiality of that data, whether they are uplifting the equipment itself or downloading data from it. If necessary it may be required to complete the Trust Data Access Statement. Further guidance may be sought on this from the Trust Information Governance department
- It is illegal to send contaminated items through the post. Decontamination procedures must be followed.
- Check with manufacturer/agent regarding procedures for returning such items and if possible request their assistance.
- A decontamination certificate must be issued.
- Where appropriate a purchase order should be included with the returned item if it is not covered by a service contract.

6.7.1 Declaration of Contamination Status (Decontamination) Certificate

See appendix 3 – form 10

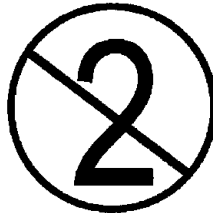
6.7.2 Trust Maintenance Contract Request Form

See appendix 3 – form 3c

Any scheduled or unscheduled servicing undertaken should be recorded in the equipment record in the Management of Medical Devices folder

6.8 Single Use Devices

**SINGLE USE MEDICAL DEVICES MUST NOT BE
REPROCESSED FOR REUSE.**



**For further guidance see MHRA document
DB 2006(04) Single-use Medical Devices: Implications
and Consequences of Reuse**

7 Transfer and Disposal of Equipment

7.1 Replacement of Equipment

This may be necessary due to the equipment being;

- Worn out or damage beyond economical repair
- Unreliable
- Clinically or technically obsolete
- Disposal due to contamination, e.g. Creutzfeldt-Jakob (CJD) etc.
- absence of manufacturer/supplier support
- Spare parts/accessories/consumables no longer available

The identification of such equipment in good time is essential so that financial arrangements can be made for replacement.

7.2 Deletion of patient sensitive data

If equipment containing patient-identifiable information is to be transferred or disposed of, the data must be deleted first. Prior to disposal the service area will need to ensure that the information is transferred to the Trust network, if this has not already been done. ICT can provide small USB Memory Stick on loan if required.

Once the information has transferred successfully, the PC/device should be certified as securely erased to an appropriate standard, such as BS ISO/IEC 15408 [24] and British HMG Infosec Standard 5, or IS5, before disposal. Data on any device should be forensically unrecoverable, i.e. patient data must be over-written.

ICT have a contract with AMI to provide these services. Liaise with ICT to contact AMI to advise them on what equipment is involved and what needs done with it. They will provide a quote and upon raising a Purchase Order, will arrange collection of the equipment, or arrange for wiping of the data for further disposal by the Trust Waste Management services.

7.3 Decommissioning

Decommissioning is the formal process for the removal of devices or equipment from service in the Trust. This may be by;

- Condemning and subsequent disposal of the equipment
- Transfer of the equipment out of the Trust

7.4 Condemning

This should be undertaken in conjunction with the Estates department. A formal form for condemnation of equipment should be completed (appendix 3 – form 11) in conjunction with Estates Operations (Estates Helpdesk). If you have access to the *Medical Device Management Interface* then you can complete and email a request for a condemnation notice automatically.

Where a ward or department wishes to condemn and scrap equipment they should notify Estates Admin (medicaldevices.gpk@belfasttrust.hscni.net) so that the asset management system record for that equipment can be updated. Estates Contracts should be contacted to have the equipment removed from any maintenance or service contracts. The area should update their local inventory record for that equipment as well.

Note: Equipment which has been condemned for scrapping must not be offered for further use.

7.5 Disposal

7.5.1 Devices being permanently taken out of service

Such Devices must be:

- Decontaminated, where possible, and a decontamination certificate (form 10) completed and retained.
- Removed from any service contract or other maintenance arrangements.
- Clearly identified as removed from service and disposed of in compliance with the statutory waste regulations where necessary, e.g. electrical or electronic waste, radiation, chemical, pharmaceutical, etc. Contact Waste Management if there are special requirements for the disposal of the equipment or for further advice and guidance

7.5.2 Devices Being Temporarily Taken Out of Service

Devices temporarily taken out of service must be removed from the clinical area or client's home and clearly labelled to indicate that they are out of use. Depending on the length of time that the equipment is out of use, it may still require periodic servicing, calibration etc, especially if intended as back-up equipment that may need to be used at short notice

7.6 Transfer of Old or Obsolete Devices

The Trust must be indemnified against future liability of medical devices that are no longer of use to the Trust and is being sold or donated. For each device being transferred Directorates must ensure that

- Transfer information is provided to the prospective recipient whether for selling or donation (see appendix 3 – form 12). Where appropriate, and depending on the risk classification of the device (section 5.4), this should include:
 - Documentation of decontamination (decontamination certificate, form 10),
 - User manuals and training requirements,
 - Service history and service manual,
 - Quality assurance test details.
- It is accompanied by a completed Trust disclaimer form ((see appendix 3 – form 13)
- The person accepting the donation should be given a copy of the permit for removal (see appendix 3 – form 14)

7.6.1 Decontamination Certificate for repairs/servicing/investigation/disposal
(See appendix 3 – form 10)

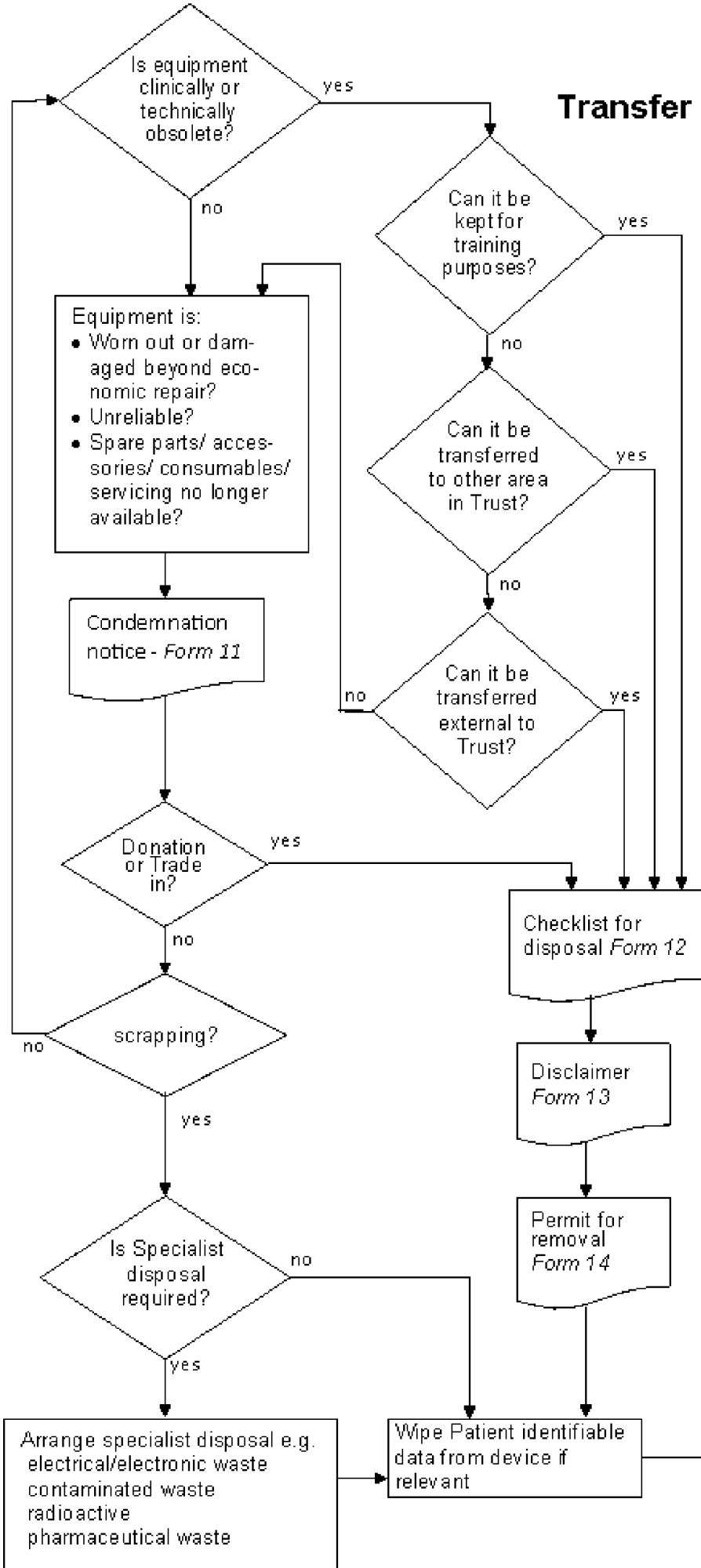
7.6.2 Condemnation & Disposal Record
(see appendix 3 – form 11)

7.6.3 Checklist for sale or transfer of ownership of a used medical device
(see appendix 3 – form 12)

7.6.4 Disclaimer for disposal Of Equipment Surplus To Requirement
(see appendix 3 – form 13)

7.6.5 Permit for Removal Of Obsolete Equipment From Belfast Trust Hospital Site
(see appendix 3 – form 14)

Transfer & Disposal flowchart



Estates should be notified to update inventory records & service contracts

On selling or donating used medical devices the following should be supplied with the equipment as a minimum:

- a clear statement that the medical device is being resold;
- documentation of decontamination;
- user manuals and training requirements;
- service history and manual;
- medical device history;
- quality assurance test details

8. Medical Device Vigilance

8.1. Adverse Incident Procedures

Procedure for Reporting Incidents involving Medical Devices within Belfast Health & Social Care Trust

Adverse Incident – *“Any event or circumstances that could have or did lead to harm, loss or damage to people, property, environment or reputation.”*

(How to Classify Adverse Incidents and Risk, HPSS April 2006)

Where an adverse or near miss incident involves a medical device the Trust’s Adverse Incident policy should be followed as normal, but there are extra steps that also need to be considered as detailed below

Failure of equipment should be reported using the Trust Incident Reporting process. This includes equipment that did cause injury or had the potential to cause injury to patients, staff or others. It is important to report even those failures that did not cause injury as they may indicate trends of failure e.g. consumables such as giving sets.

It may also be necessary to report incidents that are not due to mechanical or electrical failure if they highlight other issues such as user error, poor training or user instructions, inadequate servicing, unsuitable storage, inadequate equipment design, inappropriate local modification, etc

If a failure is just due to wear & tear and there has been no injury then this may not need to be reported but this will depend on the individual circumstances

All equipment, including disposable equipment (e.g, IV lines, pump cartridges) should be retained if it is associated with a serious incident such as a death, even if it does not appear to be directly involved.

The following steps should be followed when an equipment failure occurs:

1. Take the equipment out of action and mark it ‘Do Not Use’. Include a short description of the nature of the fault if possible. Retain any related evidence such as packaging, consumables, giving sets for pumps, etc
2. Inform your Directorate Quality & Governance manager immediately by telephone if the equipment failure had a direct impact on patient care.
3. Complete the Trust’s Adverse Incident form (paper IR1 or Datixweb) and forward to your line manager. Remember to complete all of the form including the model & make of the equipment, serial/batch numbers, & CE marking. In the community a copy of the form should also be forwarded to the relevant Community Loans Store
4. Decontaminate any device that can be decontaminated without destroying evidence and attach a Decontamination Certificate to that effect (appendix 3 form 10)
5. Wrap any devices which cannot be decontaminated in two clear bags and label them clearly, stating date of incident, incident form reference number, the fact that the equipment is not decontaminated and a description of the contents.
6. Where quarantine is not practicable, the state of the device(s) at the time of the incident should be recorded for use in any subsequent investigation, e.g. photos, sketches, etc.

7. Put a sign on any equipment which is too big to move stating 'Do not use' and include the date of the incident and the Trust incident report form reference number
8. **Whatever local action is taken, the priority should be to ensure the safety of patients, staff and clients.**
9. The reporter/line manager should complete a NIAIC (Northern Ireland Adverse Incident Centre) incident form and send this to NIAIC and copies to their Directorate Quality & Governance Manager & the Medical Devices Manager. Use the reference number on the Trust incident report form as the Trust reference number on the NIAIC form. **Do not include any details that might identify patients or clients**

The NIAIC report form is available below (appendix 3 form 15) or from the NIAIC site www.dhsspsni.gov.uk/index/hea/niaic/niaic_reporting_incidents.htm or via DATIXWEB.. Send the NIAIC report by email (or post/fax it). If the incident is very serious NIAIC may be contacted by phone and this should be followed up by a written report or email. Contact details are below

10. If you are in a specialist service (e.g. cardiology, orthopaedics, wheelchairs) that is required to report medical device related incidents to MHRA (Medicines & Healthcare products Regulatory Agency) then you must also report these to the Trust on a Trust incident reporting form, and you may also need to report these to NIAIC (Northern Ireland Adverse Centre) as well
11. Initial investigation should be undertaken by the reporting area in the first instance. The equipment may need to be retained for investigation and/or repair before being returned to the manufacturer/supplier if appropriate. The line manager should contact their Directorate Quality & Governance Manager (or Medical Devices office in Corporate Governance as per the Trust Adverse Incident policy) to arrange for release to the manufacturer/supplier
12. The Directorate Quality & Governance Manager should contact the Trust NIAIC liaison officer if they feel that the situation requires further advice and/or investigation.

DO NOT REMOVE OR RELEASE THE EQUIPMENT TO THE MANUFACTURER/SUPPLIER UNTIL NIAIC AND/OR GOVERNANCE HAVE BEEN INFORMED.

Contact details

Northern Ireland Adverse Incident Centre (NIAIC),
Safety Strategy Unit, CMO Group,
Department of Health, Room D1, Castle Buildings,
Stormont Estate,
Dundonald,
Belfast, BT4 3SQ

[REDACTED]
Email: NIAIC@dhsspsni.gov.uk

Medical Devices

Trust NIAIC Liaison Officer - [REDACTED]

Medical Devices Manager - [REDACTED]

Medical Devices Coordinator - [REDACTED]

Directorate Quality & Governance Managers

Adult Social and Primary Services
Children's Community Services
Specialist Hospitals & Women's Health
Surgery, Surgery and Specialist Services
Cancer & Specialist Medicine, Surgery and Specialist Services
Unscheduled and Acute Care

References:

BHSCT Adverse Incident Reporting Policy and Procedure including Adverse Incident Investigation Procedure (ref. TP008/08)

MDA 2009-01 (NIAIC) Under-reporting of medical device and estates related adverse incidents to the Northern Ireland Adverse Incident Centre.

MDA 2011-01(NI) All Medical Devices.(Reporting Adverse Incidents)

NIAIC (2015), NIA/2015/001, Reporting of Medical Device Adverse Incidents and Near Misses and Disseminating Alerts

NIAIC (2015), NIA/2015/002, Reporting of Estates and Facilities Adverse Incidents & Near Misses and Disseminating Alerts

8.2. Distribution of Medical Device Alerts & other Safety Alerts

NIAIC issues advice to warn health and social care providers and other users of medical devices, non-medical equipment, buildings and plant about particular problems and risks and to recommend appropriate actions to minimise such problems and risks.

Medical Device/Equipment ALERTS [MDAs, EFAs, & NIAIC Alerts] are distributed to HSS Boards, Trusts, and Agencies for direct action and for onward transmission where appropriate in accordance with local procedures. NIAIC arranges for the distribution to Primary Care Professionals. [MDA – Medical Device Alert, EFA – Estates & Facilities Alert] (NIAIC website, 2009)

Within the Belfast Health & Social Care Trust Safety Alerts will be distributed using the following system.

The **Trust SABS (Safety Alert Broadcast System) Liaison Officer** (Senior Manager, Corporate Governance) will receive the alert from NIAIC, evaluate the relevance and then pass it to the appropriate **Service Managers** (and copy to the **Directorate Governance & Quality Managers**) The Service Managers will then evaluate the alert further and pass it to their service areas. They will also ensure that a response is received from the service areas within the specific timeframe of that alert. The service areas will pass their responses to their Directorate Governance & Quality Manager who will collate these and pass them back to the **Trust SABS Liaison Officer**.

This process may also be used to disseminate warning notices and guidance from other sources such as MHRA and manufacturers' Field Safety Notices, NPSA safety alerts and NHS Estates notices. It can further be used to distribute internal safety alerts such as might be generated in the follow-up to incident investigations.

Where service areas are aware of an Independent Sector Provider (**ISP**) that is using equipment that is the subject of an alert it is recommended that our staff should bring this alert to their attention, to ensure they are aware of it. Ultimately though it is the responsibility of the ISP to act on this information

Each Service Manager is responsible for reviewing the content of alerts received and taking appropriate action within the timeframe allotted by NIAIC

Depending on the content of the notice the individual ward/department managers will be responsible for bringing the content of alerts to the attention of their staff. Such alerts should be retained for a relevant period depending on the alert so that all staff may view them via a department reading folder, staff meeting or similar.

Flow chart for dissemination of Safety Alerts and Confirmation of Actions

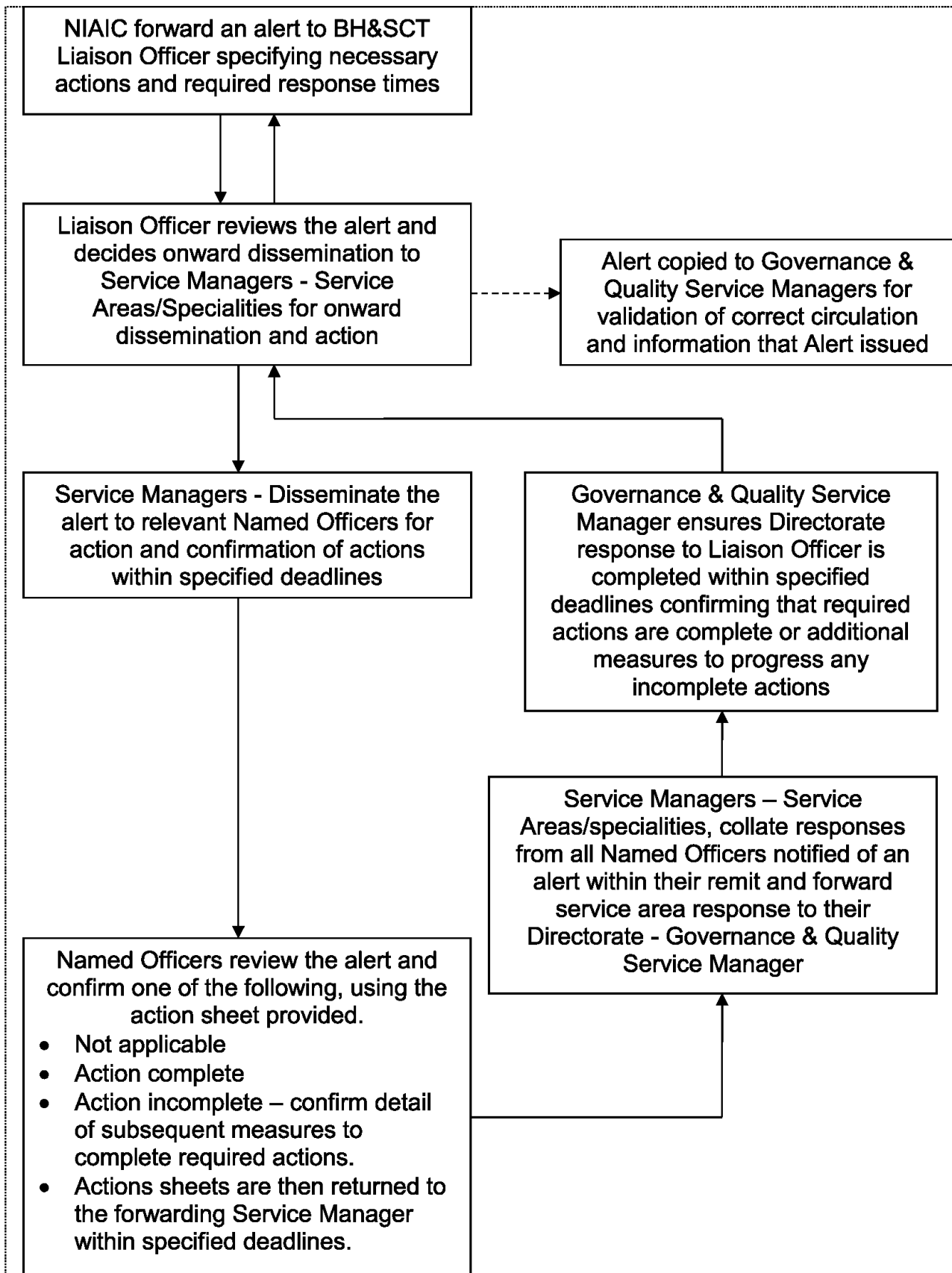


fig 3

Appendices	55
1. Medical Devices Advisory Committee Remit	56
2. Role definitions	57
2.1. Medical Devices Manager's responsibilities	
2.2. Medical Devices Coordinator's responsibilities	
2.3. Department Equipment Controller's responsibilities	
2.4. Department Equipment Assistant's responsibilities	
2.5. Community Equipment Loans Store Manager	
2.6. Community Equipment Loans Storeman	
2.7. Technical Supervisor's responsibilities	
3. Forms	
1. <u>Procurement</u>	
a. <u>Equipment Procurement Checklist</u>	65
b. <u>POCT Procurement Checklist</u>	70
2. <u>PPQ – Pre-Purchase Questionnaire</u>	73
3. <u>Part A - Registration/Acceptance form</u>	75
<u>Part B - Details of Acceptance Procedure for</u>	
<u>Newly Delivered Devices</u>	76
<u>Part C - Maintenance Contract Request Form</u>	77
4. <u>Ward/department Inventory Record of Medical Device</u>	82
5. <u>Trial/Loans Indemnity Guidance</u>	83
Form 5a - <u>Overarching Master Indemnity Agreement</u>	87
Form 5b - <u>Mia Call-Off Agreement</u>	89
6. <u>Record of Equipment on Loan to Patient/Client/Carer</u>	93
7. <u>Equipment Training and Familiarisation Schedule</u>	94
8. <u>Medical Device Training Record – Department Record</u>	95
9. <u>Medical Device Training Record – Personal Record</u>	96
10. <u>Part A - Decontamination Guidance</u>	97
<u>Part B - Declaration of Contamination Status (Decon Certificate)</u>	99
11. <u>Condemnation & Disposal Record</u>	100
12. <u>Checklist for Sale or Transfer of Ownership of a Used Medical Device</u>	101
13. <u>Disclaimer for Disposal of Equipment Surplus to Requirement</u>	102
14. <u>Permit for Removal of Obsolete Equipment from Belfast Trust</u>	
a. <u>Hospital Site</u>	103
15. <u>NIAIC Adverse Incident Report Form</u>	104
Useful Contacts	105
References	106
Belfast Trust Policies	107

Medical Devices Advisory Committee Membership & Terms of Reference

Introduction

The Trust has established a Medical Devices Advisory Committee to ensure that systems and processes are in place to properly manage the procurement, usage, maintenance and disposal of all medical devices to ensure their use and application does not create a risk to patients, clients, staff and visitors.

Objectives

- Promote ongoing improvements in Medical Devices and Equipment Management
- Reduce the risks associated with the use of medical devices and equipment
- Improve communication between all parties involved in the management of the medical devices and equipment process

Remit

The Group will:-

- Formulate Policies and Procedures
- Co-ordinate efforts towards increased compliance with the Controls Assurance Standards for Management of Medical Devices and Equipment
- Monitor Medical Devices and Equipment Management Performance
- Offer advice and assistance with regard to a wide range of medical device and equipment management issues including:-
 - ~ Co-ordination of the medical device and equipment register
 - ~ Specification, comparison & purchase
 - ~ Model standardization
 - ~ Training
 - ~ Maintenance arrangements
 - ~ Decontamination
 - ~ Decommissioning & Disposal
 - ~ Adverse Incident Investigation & Reporting

Membership

The members will be responsible for providing expert advice and for co-ordinating or undertaking work at the request of the Committee. The Committee will have the following membership from the following roles / services:

Medical Director

Co-Director, Planning & Redevelopment (Chair)

Co-Director of Information Technology

Quality & Governance Manager, Adult Social & Primary Care

Quality & Governance Manager, Specialist Hospitals & Women's Health

Quality & Governance Managers, Surgery & Specialist Services

Quality & Governance Manager, Unscheduled and Acute Care

Senior Manager, Corporate Governance Services

Senior Manager, Estates / Contracts

Podiatry Services Manager (representing AHP services, Unscheduled & Acute Care)

Consultant Scientist, Laboratories, Cancer & Specialist Services

Senior Manager, Community Child Health

Senior Infection Prevention & Control Nurse
Medical Devices Manager, Risk & Corporate governance
Head of Capital Development Finance
Senior Manager Theatres & Sterile Services

- ~ Clinical Directors and Heads of Specialist Departments will be asked to nominate representatives to serve on the committee.
- ~ All post holders and members will have nominated deputies who can attend meetings in their absence.
- ~ All appointments will be reviewed at a maximum interval of every three years.

Frequency of Meetings

The Medical Devices Advisory Committee will meet every four months.

Quorum

A quorum, consisting of either the Chairperson or the Deputy Chairperson and at least four other members, must be present for the transaction of business.

Reporting Arrangements

The Group will report to the Assurance committee on a yearly basis and present a report to the Trust Board as part of the annual report.

Terms of Reference

The Medical Devices Advisory Committee will:

- Develop Trust-wide approach to the management of medical devices ensuring that all aspects of procurement, usage, training, maintenance, decontamination and disposal are considered and assessed to ensure the safe and most effective use is made of every piece of equipment
- Provide a forum in which to discuss and agree forward action with regards to Trust-wide medical devices management issues as they emerge.
- Develop Trust-wide policy and guidelines on managing medical devices.
- Establish KPIs and annual reporting on the management of medical devices.
- Develop a Trust-wide register of all medical devices across all directorates.
- Assess the Trust needs and rationalise/standardise the use of equipment where appropriate.
- Monitor risks associated with medical devices as reported through medical device alerts and Trust risk management processes.
- Review serious untoward incidents involving medical devices, ensuring trends are identified and appropriate action is taken.
- Ensure directorates have systems in place to monitor provision of training for all users of medical devices and equipment which will support their safe and effective use.
- Develop protocols and guidelines for procurement that focus on the life cycle of medical devices to ensure that they are fit for purpose, can be appropriately decontaminated and funding is identified for servicing and testing.

Role Definitions

2.1 Medical Device Manager's Responsibilities

Responsible through the Senior Manager Corporate Governance Services for the

- Development of robust governance processes for the effective and safe management of medical devices including their decontamination.
- Support the management of information flows regarding safety alerts involving medical devices and will act as the Trust's NIAIC liaison officer in the absence of the Senior Manager Corporate Services.
- Lead on the monitoring of compliance with the decontamination of medical devices against extant guidance, standards and legislation
- Assist with the investigation of Serious Adverse Incidents involving medical devices.
- Provide support for investigation of other medical device related incidents
- Ensure the provision of and assist with the delivery of broad-based training sessions and suitable training schemes for Medical Devices Management and Decontamination.

2.2 Medical Device Coordinator's Responsibilities

Support the Medical Devices Manager in the development and implementation of robust systems for key device and equipment management which may include the following tasks.

- Training - running broad-based training sessions or organising participation in suitable training schemes.
- Management - identifying key workers in each *Directorate*/department who will keep documents up-to-date, e.g. equipment manuals, training records, safety notices and device bulletins, text books, etc.
- Information – create reports and summaries for dissemination of incident reports, compliance with KPI targets, etc
- Risk assessment - devise protocols, audit departments, apply protocols, repeat visits to ensure action is taken to reduce risk, etc. Generic risk assessments are available on the Trust Hub
- User/technical department interface - improve lines of communication between users and maintenance organisations.
- Assist with the investigation of Serious Adverse Incidents involving medical devices.
- Provide support for investigation of other medical device related incidents

2.3 Department Equipment Controller Responsibilities

There shall be an Equipment Controller for each department, ward or other area where medical devices and equipment are used. In certain instances there may need to be more than one Equipment Controller.

It is the responsibility of all service managers (& DEC"s) to ensure:

- They assess the suitability of new equipment and seek advice from the appropriate department's prior procurement (as detailed within the Medical Devices Procedures and Guidelines document).
- Acceptance of medical devices into service and involvement in commissioning and acceptance testing.

- Maintaining of an up to date inventory by liaising with Estates/ Technical Supervisor in relation to the Asset Register for registering newly delivered equipment and updating Estates with details of any updates/changes made.
- There is a record of equipment that is on-loan to other departments, hospitals and patient/clients.
- All staff within their department are suitably trained and deemed competent to use the equipment there
- The training on the use/handling/processing of medical devices & equipment is documented appropriately.
- Provision of updated and revised instructions, manuals etc to all staff within their department when the same is received from manufacturers/suppliers
- All equipment can be appropriately decontaminated in accordance with manufacturers' instructions.
- Medical Devices are decontaminated as appropriate prior to any repair, or service or investigation and this is documented.
- Equipment is adequately stored and maintained as per manufacturing instructions.
- Liaising with the Technical Supervisor with respect to all aspects of the maintenance and servicing of medical devices. Servicing contracts to be organised in conjunction with Estates Contracts
- Monitoring of the servicing arrangements from the User point of view.
- Arrangements made for servicing the equipment reflect the interests of the user, as regards accessibility, frequency and time of servicing etc.
- Collaboration with the Technical Supervisor, Estates and Supplies Department in the preparation and revision of a planned replacement programme.
- Equipment is disposed of in the appropriate manner.
- Liaison with such other departments as may be required for successful management of medical devices under their remit, e.g. ICT, Estates, Laboratories, POCT, etc
- All incidents involving medical devices are reported as per the Trust Incident Reporting system, and if necessary NIAIC are also notified.
- Safety alerts and bulletins are brought to the attention of staff in their area and appropriately actioned.
- Any identified concerns with the management of medical devices & equipment are assessed and documented on their department and directorate's risk registers as appropriate.

2.4 Department Equipment Assistant Responsibilities

There should be at least one Equipment Assistant for each department, ward or other area where medical equipment is used.

The Department Equipment Assistant is responsible to the Department Equipment Controller for the following;

- checking of equipment on a periodic basis for inventory purposes,
- for visual inspection of defects
- checking of return of on-loan devices
- user servicing as required e.g. cleaning, battery changes, calibration

Any problems affecting usability should be referred to Estates or the Technical Supervisor for repair, as appropriate

Where extra training is required this will be provided by the Trust

2.5 Community Equipment Loans Store Manager

The Community Loan stores Manager is responsible for the management of medical equipment within their area. Their duties include:

- Management of the database holding the information of medical devices in the community to ensure traceability
- Involvement in the procurement of equipment to be delivered by the department
- Ensuring the service engineers receive accurate lists of equipment requiring servicing at the recommended intervals
- Ensuring that new equipment is assessed and added to service lists if necessary
- Ensuring staff receive appropriate training to ensure correct installation of equipment
- Providing a source of technical advice

2.6 Community Equipment Loan Store Storeman

The Community Loans Store Storeman is responsible to the Community Loans Store manager for the following;

- Decontamination of equipment and checking to see if it is fit for issue
- Checking used equipment returned to the store
- Reporting defects or possible areas of concern with equipment
- Ensuring equipment is appropriately labelled as Trust property and with a Trust asset number
- Checking new equipment delivered to the store
- Arranging repair/servicing of equipment
- Completion of all relevant documentation
- Recommending to their Manager any equipment which should be condemned

2.7 Technical Supervisor Responsibilities

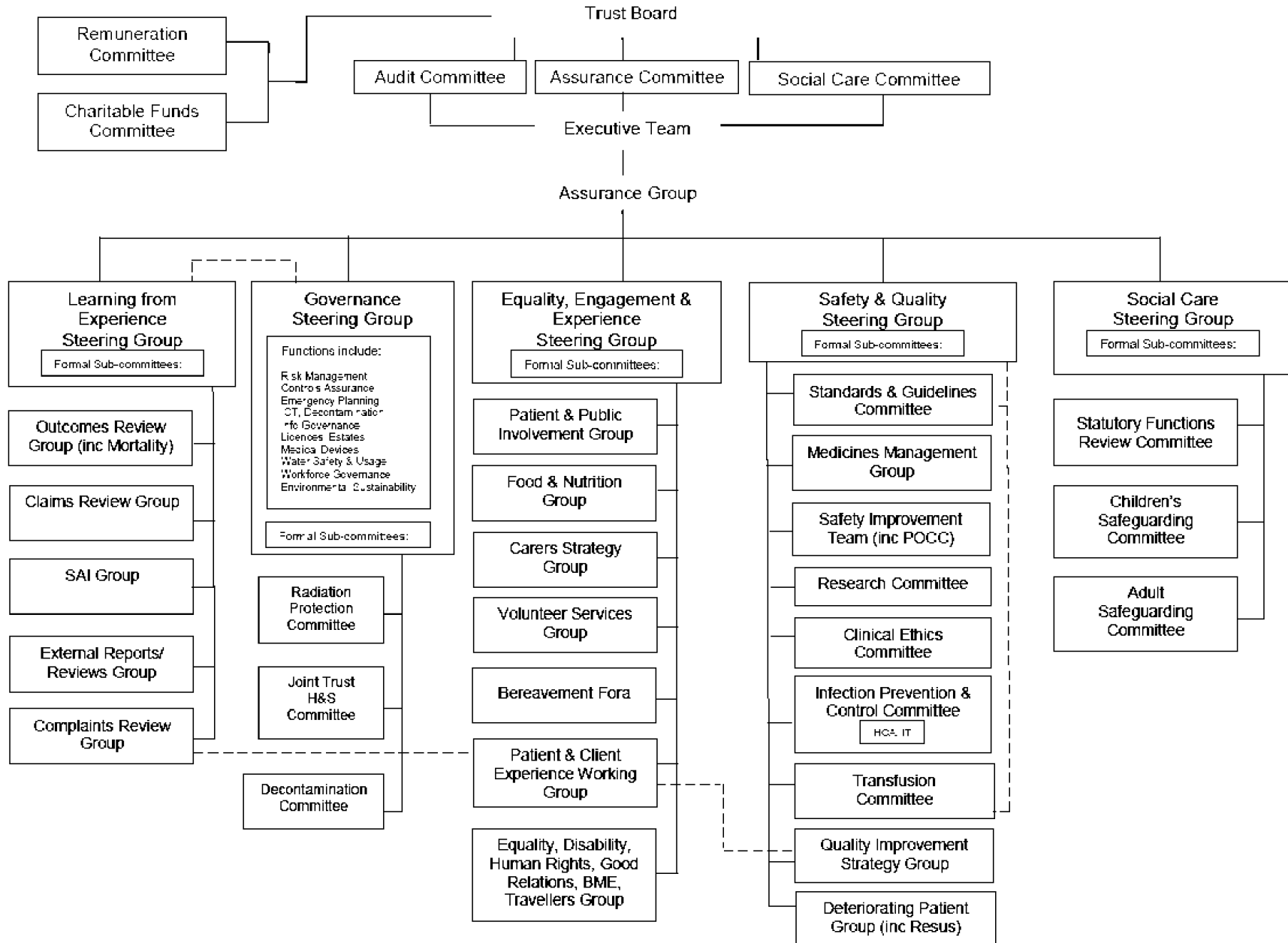
Each *Directorate* should ensure that this function is carried out which may require the support of one or more individuals, known as Technical Supervisors.

Responsibility of the Technical Supervisor includes:

- Technical advice on new devices and checking PPQ forms.
- Electrical safety of medical devices.
- Advising on appropriate maintenance and service arrangements.
- Ensuring that servicing and calibration is carried out where appropriate.
- Monitoring of service contracts.
- Liaison with Estate, Supplies, Administration and the Equipment Controllers.
- Maintaining inventories.
- Ensuring safety of medical devices on loan or trial.

This function may be carried out by Estate Services Department if required.

ASSURANCE SUB-COMMITTEE STRUCTURE



Assurance Sub-Committee STRUCTURE Jul 2016 Approved

MEDICAL DEVICES SUBGROUPS' STRUCTURE

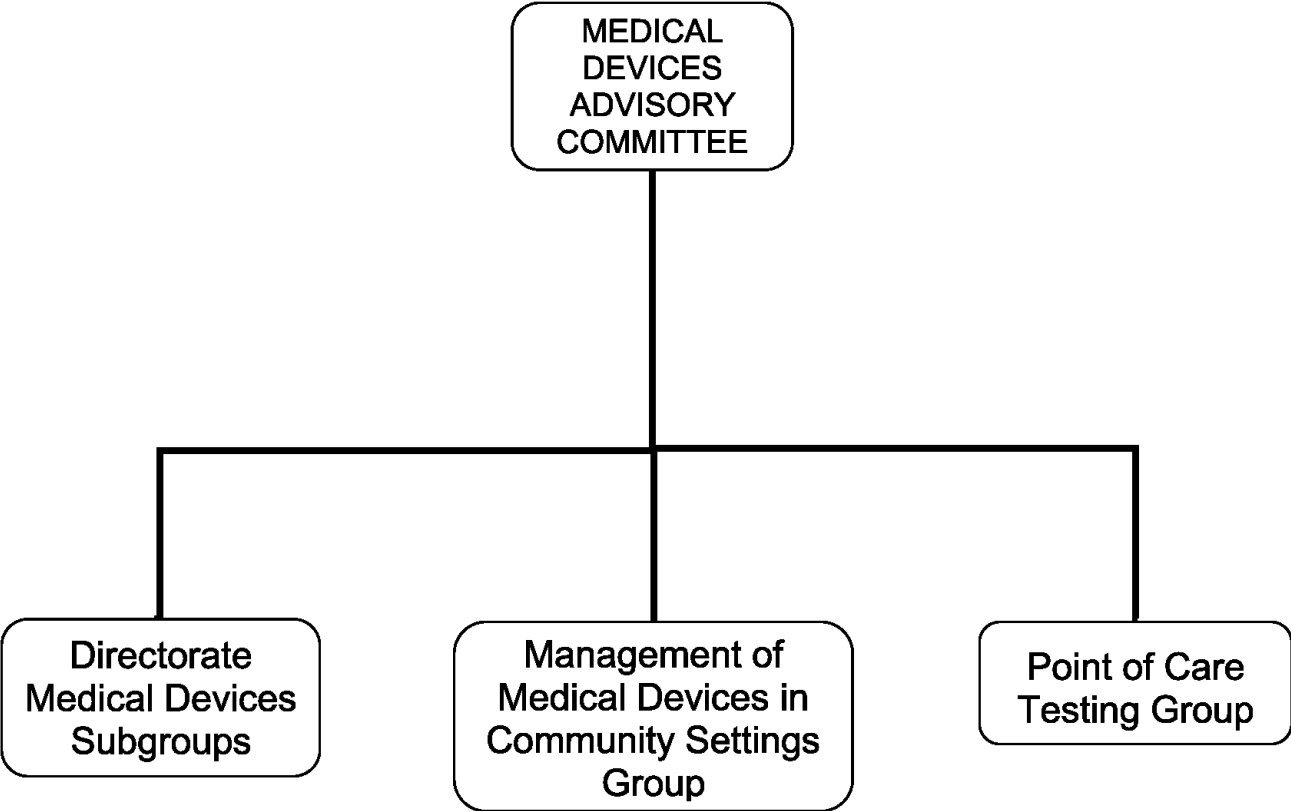


Fig 2

Forms

1.	<u>Procurement</u>	
	a. <u>Equipment Procurement Checklist</u>	65
	b. <u>POCT Procurement Checklist</u>	70
2.	<u>PPQ – Pre-Purchase Questionnaire</u>	73
3.	<u>Part A - Registration/Acceptance form</u>	75
	<u>Part B - Details of Acceptance Procedure for Newly Delivered Devices</u>	76
	<u>Part C - Maintenance Contract Request Form</u>	77
4.	<u>Ward/department Inventory Record of Medical Device</u>	82
5.	<u>Trial/Loans Indemnity Guidance</u>	83
	<u>Form 5a - Overarching Master Indemnity Agreement</u>	87
	<u>Form 5b - Mia Call-Off Agreement</u>	89
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7.	<u>Equipment Training and Familiarisation Schedule</u>	94
8.	<u>Medical Device Training Record – Department Record</u>	95
9.	<u>Medical Device Training Record – Personal Record</u>	96
10.	<u>Part A - Decontamination Guidance</u>	97
	<u>Part B - Declaration of Contamination Status (Decon Certificate)</u>	99
11.	<u>Condemnation & Disposal Record</u>	100
12.	<u>Checklist for Sale or Transfer of Ownership of a Used Medical Device</u>	101
13.	<u>Disclaimer for Disposal of Equipment Surplus to Requirement</u>	102
14.	<u>Permit for Removal of Obsolete Equipment from Belfast Trust Hospital Site</u>	103
15.	<u>NIAIC Adverse Incident Report Form</u>	104

Medical Devices Form 1a

Procurement considerations/checklist

This document is intended to be a guide when procuring new or replacement equipment. It suggests questions to consider and allows for the comparison of features and costs between different devices but it should not be considered to be definitive and it may require liaison with other services (e.g. estates, ICT, ICT, labs, etc) to complete.

For POCT (Point of Care Test) device procurement see Medical Device Form 1b

Device Information	
Device Type	
Manufacturer:	
Make/Model:	
Length of time on market:	
What similar devices already exist in the ward, department, service area or community store?	
Is this equipment on an established PALs Framework?	Yes / No / N/A
Supplier recommended life of equipment:	
Is the equipment easily upgraded should the need arise	Yes / No / N/A
Is there a latex free option?	Yes / No / N/A
Is the equipment CE marked?	Yes / No
Supplier Support	
Is there in-house Technical Support?	Yes / No / N/A
Is there a pre-existing service-maintenance contract already in place in Trust (for same or similar equipment) ?	Yes / No / N/A
Anticipated maintenance costs? (see financial information section below)	£_____
Is there satisfactory Supplier Technical Support?	Yes / No
Is there satisfactory Supplier User Support?	Yes / No
Are User Guides and instructions suitable?	Yes / No
Have these been reviewed by the service area	Yes / No
Functionality	
Does the device meet all your essential / desired intended functions	Yes / No
Does use of this equipment require a risk assessment?	Yes / No
Infection Control	
Is the device easy to clean/decontaminate?	Yes / No
Are special facilities needed?	Yes / No
<i>If yes send SSD Decontamination Questionnaire (available from SSD Manager) with PPQ form</i>	
Have you consulted with Infection Prevention Control Team?	Yes / No / N/A
Detail any recommendations made:	
Previous Performance (liaise with Estates, ICT, Labs, IPC, H&S, Corporate Governance as required)	
Has the item been bought by the Trust before?	Yes / No
Have there been any user problems?	Yes / No
Is the medical device recommended by peer services (locally/regionally/nationally)?	Yes / No

Medical Devices Form 1a

Procurement considerations/checklist

Special Requirements (liaise with Estates, ICT, Labs, IPC, H&S, Corporate Governance as required)

Does the equipment have any special requirements (e.g. lighting, water, power, accommodation, connectivity, etc?) If so specify here or in an attachment Yes / No

ICT Requirements

Consideration should be given to the following in consultation with ICT governance and the Information Commissioner's Office (ICO)

- Adherence to standards for connectivity to the Trust network and onwards to the Internet
- Adherence to the ICT technology standards
- Adherence to standards for information Governance
- Identification of Information Assets Owners
- Systems which store confidential data should be recorded centrally
- Decommissioning should include the removal of all confidential data
- Adherence to security standards either the HSC ICT policy or ISO 27001 standard
- Adherence to standards for data exchange (e.g. HL7)
- A business continuity plan for critical devices if appropriate
- Risk assessment if the system is cannot meet this requirement
- Risk assessment for management of the device may require a Privacy Impact Assessment (PIA) to determine what risks may relate to the data held on the equipment
- Clear documented roles and responsibilities for the safe operation and support of the device

Further information

Does the device meet current relevant recommended standards & guidelines? Yes / No

Does the device have the Desirable features as listed in paragraphs 4.31 - 4.38 of report of the Expert Working Group on Alarms on Clinical Monitors (MDA 1995)? Yes / No / N/A

This includes:

- secure controls (physical key/keypad lock)
- minimising of false alarms
- clear indicator of alarm deactivation,
- data logging include record of setting changes)

Medical Devices Form 1a
Procurement considerations/checklist

Any other essential features?

Any other desired features?

Medical Device Form 1

Procurement Device/Equipment Costing

Make/Model:		
Financial Information (This page can be complete by the supplier)		
	Cost (monthly/annually)	Comments
List price	£	
Offer Price Detail any discounts/ trade-in offered.	£	
Service Manual & Spare parts Lists Availability/cost		
Installation/Set-Up/Training costs		
Any capital works required with regards to installation		
Installation costs inc ICT / network costs	£	
User training	£	
Technical support staff training	£	
Running costs		
Consumables piece (each item)	£	
How many will be required in one year?		
Accessories (eg probes, leads, PPE)	£ £	
Decontamination costs	£	
Annual Service & Maintenance costs		
Comprehensive contract	£	
Maintenance only	£	
Cost of emergency call outs	£	
Response Times		
Loan device available in case of failure.	Yes / No	
Disposal overheads	£	
Miscellaneous other Costs	£	

This is a guide for internal Trust use only. It is not to be used for device selection on PALs / BSO CAG panels

Summary Scoring and Conclusion (liaise with technical support as required)															
Make / Model:															
Score each section below: 1 = poor, 2=below average, 3=average, 4=good, 5 = excellent															
Ease of use					Ease of <u>user</u> servicing (inc costs)					Confidence in Supplier					
1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	n/a
Build Quality					Problems					Repair & Maintenance Costs					
1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Features (range of features/options)					Consumable costs					Accessories costs					
1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	
Compatibility with existing devices					Compliance with specification and fitness for purpose					Overall score:					
1	2	3	4	5	1	2	3	4	5						
Is the item recommended for purchase?														Yes	No <input type="checkbox"/>
Form Completed by:															
Date:															
Sent to Service Manager for consideration														Yes <input type="checkbox"/>	N/A <input type="checkbox"/>
Other comments:															

For further guidance information refer to the Medical Devices Policy and the Medical Devices Procedures & guidelines, available on the Trust intranet

Proposal for New or Replacement Point of Care Testing (POCT) Applications in the Belfast Trust

Introduction

The Belfast Trust policies^{1,2} for the Medical Devices and POCT describe the principles of how the Trust will discharge its responsibilities with regard to the governance of POCT. One important aspect of this is the role of the POCT committee in assessing new and existing POCT applications within the Trust.

Definition:

Within this document POCT is defined "An analytical test undertaken by a member of the healthcare team, or by a non-medical individual in a setting distinct from a normal hospital laboratory."

Scope and purpose:

This checklist is intended to prompt consideration of the various elements required for a new or replacement POCT application in order that the POCT committee can assess compliance with Trust policy and relevant guidelines^{2,3,4,5}. The information supplied should be supported by additional literature from peer reviewed publications and suppliers.

It is recommended that Trust policy and referenced guidelines on POCT are reviewed and appropriate laboratory specialists are consulted in completing this pro forma.

1. Baseline Information:

Proposed location of testing:	
Clinical Specialty:	
Analyte(s) or test(s) proposed:	
Specimen requirements (circle):	Whole blood Serum Plasma Urine Other:
Patient groups to which POCT would be applicable:	
Estimated number of tests :	Daily: weekly:
Describe briefly the current limitations of the conventional laboratory service for the proposed testing:	
Laboratory confirmation that the relevant discipline is unable to meet clinical or operational requirements for the proposed testing:	LAB USE ONLY

2. Objectives:

Please summarise the main objectives for the POCT service and how it will impact on patient care:

3. Testing: Indicate how the following tasks will addressed:	
Testing:	
Training:	
Maintenance:	
Quality Assurance :	
Record keeping:	
Troubleshooting:	
4. Accommodation::	
Instrument :	Portable y/n Static (give footprint)
Operator space required:	
Storage space for the device(s), consumables, reagents.	
Services required (power, water, refrigeration, IT, SSD):	
Health and safety / control of infection issues:	
5. Costs:	
Has recurrent funding been identified	Give source
Initial purchase cost:	
Consumable costs:	
IT and other installation costs:	
Internal Quality Control costs:	
External Quality Assurance costs:	
Maintenance/service contract:	
Waste disposal costs:	
6. Test /Instrument specification:	
Principle of the assay:	
Reagent stability:	
Imprecision:	
Range:	
functional sensitivity:	
Time to result:	
Treatment Criteria (+/- ve) following results:	
Reagent shelf-life:	
Device lifespan:	
Lab Test conformity	
Known interferences:	
Instrument warnings:	
Sample volume:	
7. Candidate devices:	
(i) Simple disposable (eg dipstick)	
(ii) Meter type (eg glucometer)	
(iii) Analytical Instrument (eg blood gas analyser)	
8. Connectivity specification:	

9. Evaluation: please attach results of any in-house evaluation which has been carried out, literature references, particularly MHRA/PASA reports.	Number/nature of attachments enclosed: (eg articles, evaluations, etc)
--	--

References.

1. Belfast Trust Medical Devices Policy & Procedures
2. Belfast Trust POCT (Point of Care Testing) Policy & Procedures
3. Royal College of Pathologists (<http://www.rcpath.org>)
4. ACB (The Association for Clinical Biochemistry <http://www.acb.org.uk/>)
5. IBMS (The Institute of Biomedical Science <http://www.ibms.org>)
6. Regional POCT Policy

This form is intended to supply prospective purchasers with information about equipment being considered for purchase. It is intended principally for pre-purchase information on electrical medical, dental, ophthalmic and laboratory equipment. The form may also be used for other products, including non-electrical items, and to give information prior to equipment being supplied on loan, in which case not all the questions will be relevant. Please ensure all relevant questions are answered.

<i>For issue and completion by purchaser:</i> PPQ Master Reference:	
<i>A unique reference (preferably ten characters maximum) must be given by the supplier:</i> Supplier's Reference:	
Generic Device Type:	Equipment Model:
Country of Origin:	Manufacturer:
Supplier:	Telephone No:
Fax No:	e-mail:

CE MARKING

1. a) Does the product carry the CE marking? YES NO

b) If YES, to which EC Directive(s):

i) Active Implantable Medical Devices Directive (90/385/EEC) YES

ii) Medical Devices Directive (93/42/EEC) YES

If YES, state classification of device (93/42/EEC Annex IX)

iii) *In Vitro* Diagnostic Medical Devices Directive (98/79/EC) YES

If YES, is the device: For self-testing? YES Covered by Annex II: List A? YES List B? YES NO

For ii) and iii) above, Identification No. of Notified Body, if applicable

iv) EMC Directive (89/336/EEC or superseding directive) YES

v) Low Voltage Directive (73/23/EEC) YES

vi) Other Directive(s) (please specify)

2. a) Is the product a 'custom-made device' (93/42/EEC)? YES NO

b) Is the product intended for 'clinical investigation' (93/42/EEC) or 'performance evaluation' (98/79/EC)? YES NO

If YES to a) or b) above, does the device comply with the UK Medical Devices Regulations? YES NO

MANAGEMENT SYSTEM STANDARDS

3. a) Is the manufacturer currently registered to any management system standards (eg ISO 9001, ISO 14001, ISO 13485)? YES NO

If YES, please state the standard(s) and certification body:

b) Is the supplier's service and repair organisation currently registered to any management system standards? YES NO

If YES, please state the standard(s) and certification body:

SAFETY STANDARDS

4. For products not CE marked to 1 b) i), ii) or iii) above, with which safety standard(s) does the product comply?

Standard	Test House	Certificate Number	Date

SERVICE / SPARES / INSTALLATION

5. Is service/repair information available? YES NO If NOT f.o.c. please state current price Indicate contents below:

<i>(Please state YES, NO or N/A)</i>	Full circuit diagrams		Fault finding procedure		Preventative maintenance	
	Repair information		Spare parts listing		List of special tools/test equipment/etc	

If YES, please state whether also available on: Disk Website If Web, please state address

6. a) In addition to the service/repair information/manual, will training be required before competent technical personnel can provide:

<i>(Please state YES, NO or N/A)</i>	First-line maintenance		Calibration	
	Planned preventative maintenance		Repair	

b) Is the supplier able to provide this training for the purchaser's or a third party's technical personnel? YES NO

If YES, will this be free of charge? Or chargeable?

If NO, please indicate if details of an organisation that is able to provide this training are available on request? YES NO

Supplier's Reference:

- c) Is the provision of service/repair information conditional upon completion of training? YES NO
- d) In order to undertake maintenance/repair/calibration, is any special software/test equipment/tooling required? YES NO
- If YES, please indicate that details of special software/test equipment/tooling are provided on a separate sheet: YES
- 7. a) Is the supplier able to provide an 'as required' repair/maintenance service in the UK? YES NO
- b) Is the supplier able to provide a contract repair/maintenance service? YES NO
- If YES, please confirm that details of repair/maintenance contracts are provided on a separate sheet. YES

- c) i) If repairs are normally performed by the supplier on the purchaser's site, please state typical response time:
- ii) If repairs are performed off-site, where will these be carried out?
Company: Location: Typical turnaround time:
- iii) Is free of charge loan equipment normally available? YES NO

- 8. Please state if repair parts will be available to the purchaser's or a third party's suitably trained and equipped personnel: YES NO
- If YES, is the supply of repair parts conditional upon acquisition of repair information? YES Or training? YES NO

9. Please indicate when this model was first placed on the market:

- 10. a) For how many years from the date of last manufacture is the supply of spare parts guaranteed?
- b) Is the product still in current production? YES NO If NO, indicate year of last manufacture:

- 11. Is installation necessary? YES NO
- If YES, please confirm that details of all services required are provided on a separate sheet: YES

12. Will software upgrades be notified? N/A YES NO

IONISING RADIATION

13. Does the product contain a source of ionising radiation or is it capable of emitting ionising radiation? YES NO

DECONTAMINATION / REPROCESSING

- 14. a) i) Will the item be reprocessed (cleaned, disinfected, sterilised)? YES NO If NO, go to Question 15.
- ii) If YES, is the item intended to be: Non-sterile for single use Sterilised Disinfected Other
- iii) Is there a recommended maximum number of uses? YES NO If YES, please state:
- iv) Are decontamination/reprocessing instructions supplied? YES NO
- v) Are instructions available for safe disposal? YES NO
- b) i) Is manual cleaning the only cleaning method specified before further reprocessing? YES NO
- ii) What is the maximum temperature that can be used for thermal disinfection? Temp:
- iii) Are there any restrictions on detergent/disinfectant types? YES NO If YES, please state:
- iv) Can the item withstand autoclaving at 137 °C for 3 mins? YES NO
- v) Is the item compatible with other sterilization methods? YES NO If YES, please state:
- vi) Does reprocessing require the use of specified equipment? YES NO
- If YES, please state equipment type (eg containers, processors, etc) and, where appropriate, parameters of operation (eg temp, pressure, etc):

- c) i) Are tools required to aid dismantling/reassembly, or are lubricants required? YES NO
- ii) If YES, are they supplied with the device or available optionally? Supplied Optional Neither
- d) Is decontamination/reprocessing training available? YES NO If YES will this be: Free of charge? Chargeable?
- e) Are reprocessing instructions available on the Web? YES NO If YES, please state address:

WARRANTY

15. Please confirm that a copy of the warranty is provided on a separate sheet: YES

DECLARATION

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

Name: <input type="text"/>	Position: <input type="text"/>
Company/Address: <input type="text"/>	Date: <input type="text"/>

CAPITAL ASSET/MEDICAL DEVICE FORM - Part B
Acceptance Test Details

(Please use in conjunction with and attach to Form 3 Part A)

Please tick as applicable

Equipment make/model: _____

Cost centre: _____

Location (where equipment is to be used/stored): _____

If more detailed acceptance checks are required locally these may be attached to this form

1	Delivery Checks			
		Y N		Y N
	Delivery note corresponds with order?	<input type="checkbox"/> <input type="checkbox"/>	User/instruction manual supplied	<input type="checkbox"/> <input type="checkbox"/>
	Outer packaging undamaged?	<input type="checkbox"/> <input type="checkbox"/>	Maintenance manual supplied	<input type="checkbox"/> <input type="checkbox"/>
	Inner packaging undamaged?	<input type="checkbox"/> <input type="checkbox"/>	Decontamination information supplied	<input type="checkbox"/> <input type="checkbox"/>
	Device corresponds with order?	<input type="checkbox"/> <input type="checkbox"/>	Test certificate supplied	<input type="checkbox"/> <input type="checkbox"/>
	All accessories supplied?	<input type="checkbox"/> <input type="checkbox"/>	Warranty documentation supplied	<input type="checkbox"/> <input type="checkbox"/>
2	Functional Checks Assemble and switch on (following instruction manual)			
	Indicator lights illuminate	<input type="checkbox"/> <input type="checkbox"/>	Device passes self test routine	<input type="checkbox"/> <input type="checkbox"/>
	Display corresponds with manual	<input type="checkbox"/> <input type="checkbox"/>	Moving parts operate as required	<input type="checkbox"/> <input type="checkbox"/>
			Controls operate device as required	<input type="checkbox"/> <input type="checkbox"/>
3	Training			
	All users have access to manufacturers' instructions	<input type="checkbox"/> <input type="checkbox"/>	All users have received instructions on decontamination of the device	<input type="checkbox"/> <input type="checkbox"/>
	All users have received instructions on use of the device	<input type="checkbox"/> <input type="checkbox"/>	New device notice attached (if applicable)	<input type="checkbox"/> <input type="checkbox"/>
4	Electrical Safety Test Checks – Acute areas – electrical testing will be arranged by Estates on rolling programme Community areas – use checks below			
	Visual inspection	<input type="checkbox"/>	Earth continuity	<input type="checkbox"/>
	Fuse Rating	<input type="checkbox"/>	Earth Leakage	<input type="checkbox"/>
	PAT test	<input type="checkbox"/>	Appropriate Calibration & Commissioning	
	Electrical safety class: _____	<input type="checkbox"/>	Tests carried out by manufacturer's Agent	<input type="checkbox"/>
	Type: _____	<input type="checkbox"/>		
	Insulation resistance	<input type="checkbox"/>	Tester's Signature: _____	
			Date: _____	
5	Performance Checks – if required additional checklists should be completed			
	Additional checklists attached? <input type="checkbox"/> (details) _____			

6	Declaration of device ready for use			
	Equipment controller/coordinator/stores manager		Technical Supervisor/Clinical engineer	
	Name: _____		Name: _____	
	Signature: _____		Signature: _____	
	Date: _____		Date: _____	

Belfast Health and Social Care Trust Maintenance Contract Request Form

The Estates Department is responsible for placing maintenance contracts to cover maintenance of general equipment and medical devices throughout the Trust.

In order to provide this service, it is essential that Department Equipment Controllers (DECs) liaise with Estates to ensure that all new and existing equipment is recorded on their local inventory records and also on the Trust's Asset Register. Equipment should be labelled with Asset ID (HIN) labels as issued by Estates. The DEC should also ensure (in conjunction with Estates), that a service contract is arranged for the servicing of their equipment.

The DEC should also ensure that Estates are notified with details of any changes to the equipment, e.g. disposal, transfer etc.

The Estates Department is the budget holder for all maintenance contracts, however it doesn't have a budget to cover maintenance of new equipment or equipment which has not previously been covered under a maintenance contract. In such circumstances, a transfer of funding will be necessary. Funding may not be required for replacement equipment, providing that a maintenance contract was previously in place and existing funding is sufficient.

It will not be possible to raise orders to cover a new contract arrangement until it has been confirmed that necessary funds have been transferred from the relevant departmental budget to the Estates Contracts budget.

The level of funding will be advised by Estates when quotations have been received. Sufficient funds will have to be transferred to cover the cost for routine maintenance and also the estimated costs of repairs.

This document sets out the process to be followed in such instances. It requires the need to be identified, costs to be obtained and necessary funding to be transferred to allow maintenance contracts to be placed within budgetary constraints.

Further information and advice may be obtained by contacting the Estates Contracts Section at Musgrave Park Hospital.

Title	Email	Telephone No
Divisional Manager Contracts	harry.gordon@belfasttrust.hscni.net	02895048954
Contracts Officer	nigel.anderson@belfasttrust.hscni.net	02895046971
Contracts Officer	naomi.bishop@belfasttrust.hscni.net	02895047313
Contracts Officer	paulX.wilson@belfasttrust.hscni.net	02895044144
Contracts Officer	michaelh.tumelty@belfasttrust.hscni.net	02895045613

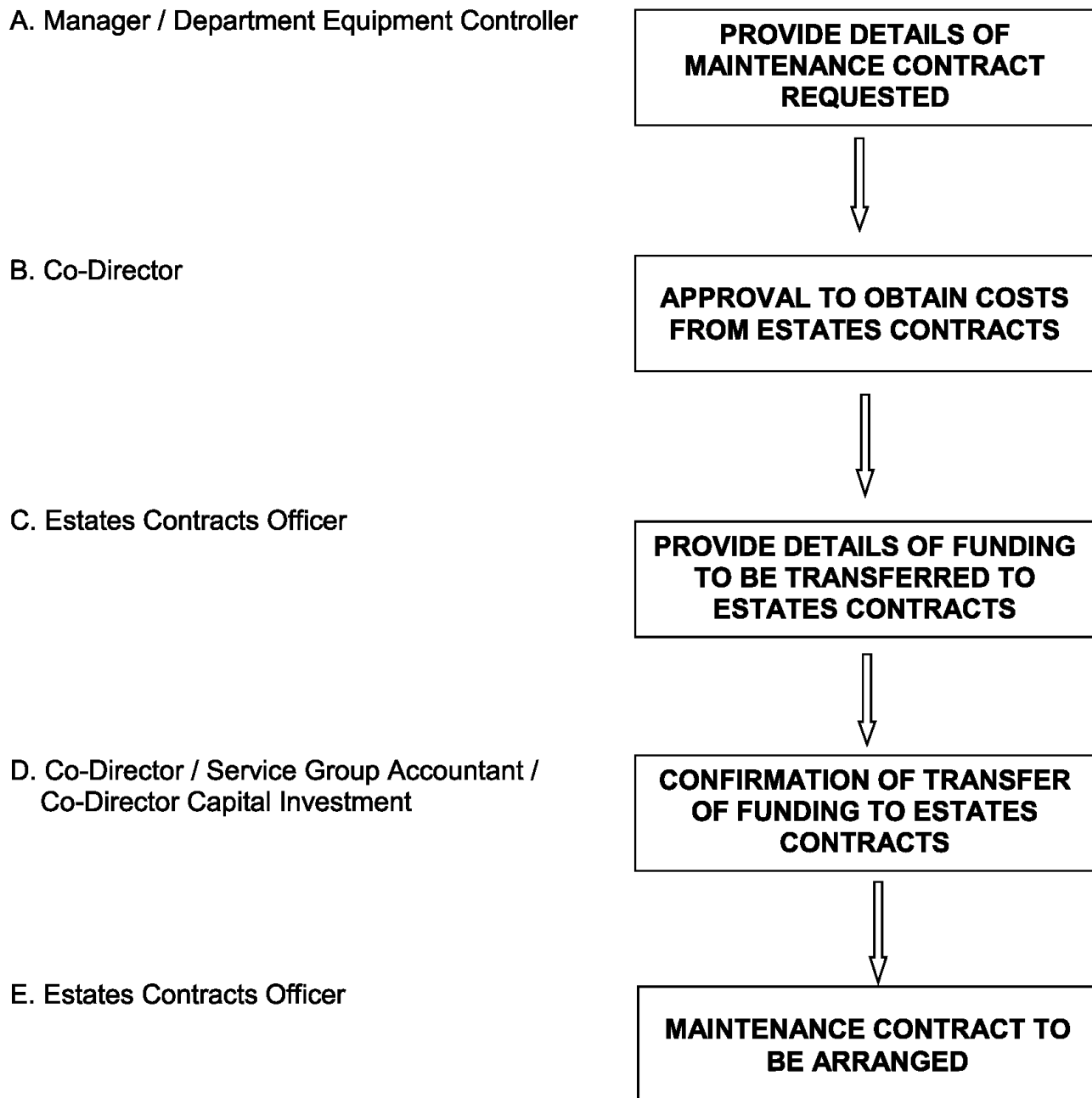
A - Details of Contract Requested	
Brief Description of Equipment:	
Equipment Schedule:	Full details to be included in the attached Equipment Schedule.
Preferred Start Date:	
Contract Duration: -Period of Contract OR -Long term	
Preferred Contractor: -Contact Person -Contractor Name -Address -Telephone -e-mail address	
Is the Contractor preferred due to “sole-provider” status? If yes, please provide details.	
Is the Contractor preferred due to a desire to retain warranty cover? If yes, please provide details.	
Preferred Level of Cover e.g. PPM only / Fully Comp / Other:	
Suggested No of Service Visits PA:	
Specification / Minimal Requirements e.g. MHRA or other requirements:	
Manager / DEC (BLOCK CAPITALS)	Manager / DEC (SIGNATURE)
Telephone No	E-mail Address
	Date

B - Approval to obtain costs:	YES / NO
Co Director (BLOCK CAPITALS)	Co Director (SIGNATURE)
	Date

C – Details of contract/funding requirements:	
Contractor	
Level of Cover / No of service visits PA	
Basic contract cost	
Total funding to be transferred to Estates Contracts to include callouts & repairs	
Contracts Officer (BLOCK CAPITALS)	Contracts Officer (SIGNATURE)
	Date

D – Confirmation of transfer of funding to Estates /Approval to proceed.	
Total funding to be transferred to Estates Contracts on a re-current basis	
Co-Director (BLOCK CAPITALS)	Co-Director (SIGNATURE)
	Date
Service Group Accountant (CAPITALS)	Service Group Accountant (SIGNATURE)
	Date
Co-Director Capital Investment (CAPITALS)	Co-Director Capital Investment (SIGNATURE)
	Date

Maintenance Contract Approval Process



Indemnity Guidance Summary & Forms

Guidance Summary on the Use of the Indemnity Forms for Loans, Trials and Free Issues of Equipment

This guidance focuses on ensuring that appropriate indemnity arrangements are in place when equipment is supplied as a loan, trial or a free issue (gift) from a supplier.

Use the flowchart to decide whether you need to use an **MIA Call-Off Agreement** form or not. It is important to first consider how the equipment has come into the Trust.

The **MIA Call-Off Agreement** form is *not* needed if:

- the equipment is being supplied for study in a **clinical investigation (research) study**. In Clinical Research trials there are specific issues that need to be addressed outside the scope of this guidance and you should consult with the Research Department, and see **§3.12** below. If the equipment is already CE marked and is supplied on loan for its intended purpose to assist in a trial, eg ECG or blood pressure monitoring, then that loan equipment should have the appropriate indemnity agreement arranged as below
- the equipment has been brought in for **demonstration** only by representatives of firms to staff, provided:
 - ~ The device is not connected to a patient.
 - ~ There is no radiation hazard (lasers, etc.).
 - ~ There are no services required (other than a 13 amp socket or piped medical gas)
 - ~ There are no other special requirements.
 - ~ The equipment is removed from the Trust after the demonstration

The **MIA Call-Off Agreement** must be completed:

- If the equipment is supplied as a **loan** or a **non-research trial** (e.g. if it suitable for a service area and their patients/clients)
- If the equipment is a **free issue or gift**.

If the equipment is a loan, non-research trial or gift then it is important that all relevant staff (end-users, IT, labs etc) in the service area are aware of its arrival and purpose, that staff are trained, and maintenance and decontamination arrangements are in place. This is particularly important if a practitioner is trialling a device to assess its suitability for purchase and has received it direct from a supplier.

Although there is no specific option for a review of the loan or trial the service area and supplier may wish to consider adding this to the form. The form may also need to be amended and signed again if there are any significant changes to the conditions of any loan or trial. In any event the specific duration of the loan should be included in the MIA Call-Off Agreement .

The relevant Indemnity Form should be completed by the area sourcing the equipment. Who the most appropriate Line Manager or Service Manager will be depends on whether the equipment is to be used in only one ward or department or across several locations.

At the start of the process proof of the Supplier's public and product liability insurance must be shown, which included checking for its validity in Northern Ireland. The indemnity insurance must be in the name of whoever signs Form A or B. This will usually be the Supplier but may be in the name of the manufacturer where a Supplier is acting as their agent. On expiry of the insurance, proof of renewal should be obtained from the Supplier (or

Manufacturer, where the Supplier is acting as an agent). Arrangements should be made for review of the public liability insurance certificate on an annual basis.

The Consultant or the manager of the Service Speciality/Area must:

- Ensure that the supplier's National Indemnity Register entry has been checked (see table below) and that the supplier has valid public liability insurance for Northern Ireland
- Ensure that **MIA Call-Off Agreement** (*appendix 3 – form 5.2*) has been completed prior to the device going into service. This must be completed each time there is an issue of equipment
- Copies of this should be retained by the service area and the supplier.
- Ensure that adequate arrangements have been made for the acceptance of the equipment including asset registration and acceptance checks, staff training, decontamination and servicing as required.

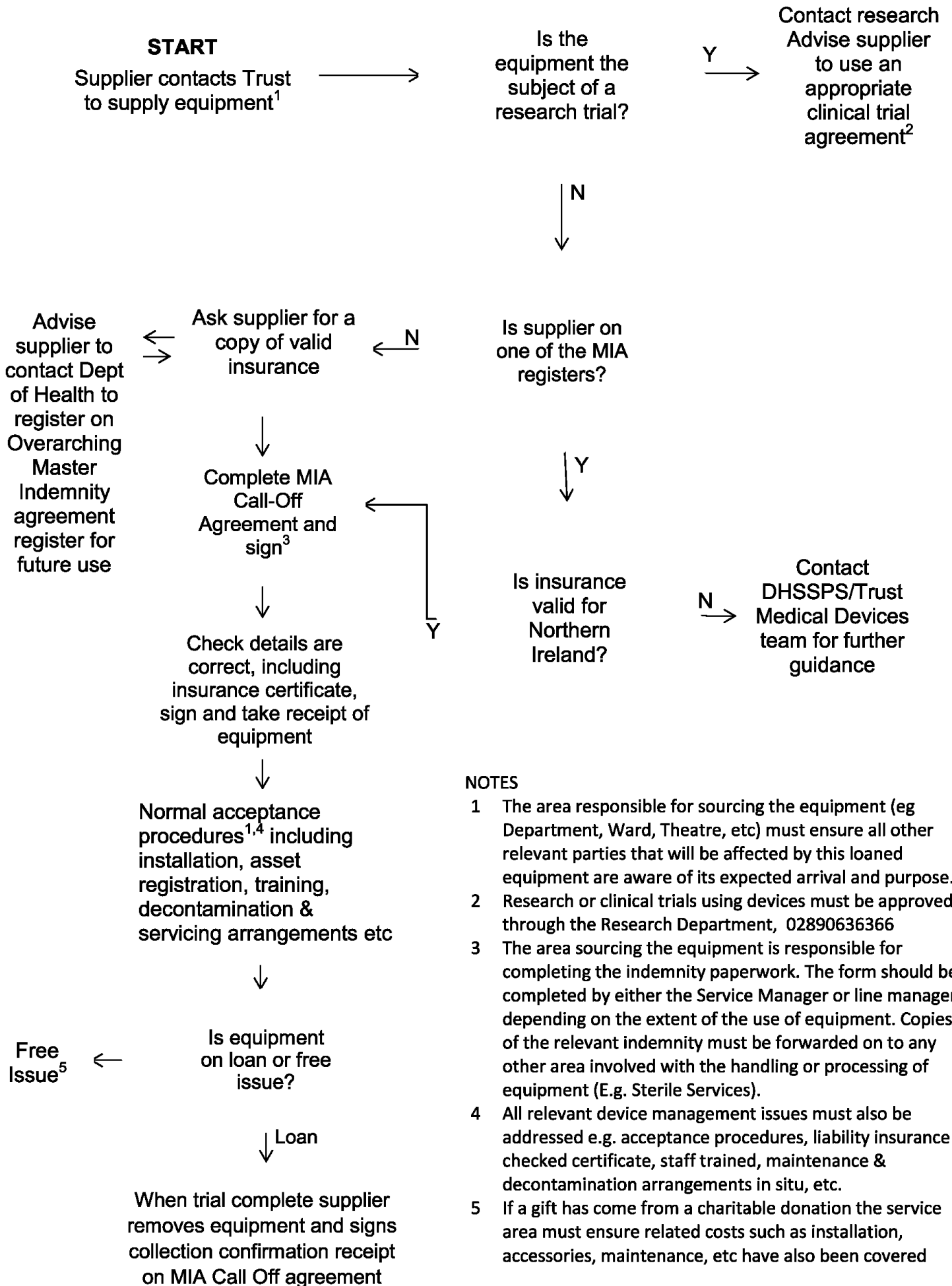
England	www.gov.uk/government/publications/master-indemnity-agreement-mia
Scotland	www.hfs.scot.nhs.uk/online-services/master-indemnity-agreement
Wales	www.whs.wales.nhs.uk/supply/masterindemnity

Although the indemnity forms provide protection to the Trust arising from the correct use of the equipment the Trust is still liable for the cost of repairing equipment (except where caused by the manufacturer/supplier or where otherwise arranged).

Where surgical instrumentation can be received by different service areas during the lifecycle of the equipment, e.g. theatres and Sterile Services Departments (CDU or EDU), local agreement must be made as to who is to complete the appropriate indemnity forms

Blank copies of the indemnity forms can be downloaded from the policies section of the Trust Intranet or from the MHRA

<https://www.gov.uk/government/publications/master-indemnity-agreement-mia>



NOTES

- 1 The area responsible for sourcing the equipment (eg Department, Ward, Theatre, etc) must ensure all other relevant parties that will be affected by this loaned equipment are aware of its expected arrival and purpose.
- 2 Research or clinical trials using devices must be approved through the Research Department, 02890636366
- 3 The area sourcing the equipment is responsible for completing the indemnity paperwork. The form should be completed by either the Service Manager or line manager depending on the extent of the use of equipment. Copies of the relevant indemnity must be forwarded on to any other area involved with the handling or processing of equipment (E.g. Sterile Services).
- 4 All relevant device management issues must also be addressed e.g. acceptance procedures, liability insurance checked certificate, staff trained, maintenance & decontamination arrangements in situ, etc.
- 5 If a gift has come from a charitable donation the service area must ensure related costs such as installation, accessories, maintenance, etc have also been covered

OVERARCHING MASTER INDEMNITY AGREEMENT

Company Name: (“Supplier”)			
Company Registration No:			
Address:			Postcode:
Contact Name:			
Contact E-Mail:			
Telephone No.:			
MIA No: (to be allocated and inserted by the Department of Health at the time of its signature)			

1.1 In consideration of the Department of Health making available the Supplier’s details as part of the Master Indemnity Agreement Register published at: <https://www.gov.uk/government/publications/master-indemnity-agreement-mia>., the Supplier undertakes that:

a. It will comply with the then current version of Master Indemnity Agreement Terms and Conditions as published by the Department for Health from time to time on the gov.uk website when providing any Equipment to the National Health Service and that such terms and conditions will form part of any MIA Call-Off Agreement with the relevant Authority to which any Equipment is supplied (to include on both a loan and transfer basis).

b. Any public liability and product liability insurance information (in respect of public liability and product liability covering the Equipment with the minimum cover per claim of five million pounds (GBP) (£5,000,000)) together with any other information provided to the Department of Health is accurate and will be kept up-to-date to ensure that the Department of Health always has copies of the Supplier’s current insurance policy details (to include confirmation of all renewals and policy changes) and company details (to include prompt notification of any name changes) accompanied with relevant supporting documentation.

c. It will not supply any Equipment to an Authority pursuant to an MIA Call-Off Agreement unless that Equipment is covered by appropriate insurance arrangements in accordance with the insurance requirements set out in the applicable Master Indemnity Agreement Terms and Conditions.

d. The Department of Health may make publically available (to include, without limitation, by sharing with other NHS organisations and other relevant public sector organisations within the United Kingdom and by publishing information on the gov.uk website) this Overarching Master Indemnity

Agreement and any information provided to the Department of Health by the Supplier under and/or in connection with this Overarching Master Indemnity Agreement.

e. It is a properly constituted entity fully empowered by the terms of its constitutional documents to enter into this Overarching Master Indemnity Agreement and has obtained any required consents or approvals.

1.2 Any defined terms used above shall have the meaning set out in the Master Indemnity Agreement Terms and Conditions. Any reference to the Department of Health shall be deemed to include a reference to the Secretary of State for Health.

1.3 The contact details for the Department of Health in connection with this Overarching Master Indemnity Agreement shall be as set out in the Master Indemnity Agreement Guidance Notes published on the gov.uk website by the Department of Health.

1.4 This Overarching Master Indemnity Agreement, and any dispute or claim arising out of or in connection with it or its subject matter (including any non-contractual claims), shall be governed by, and construed in accordance with, the laws of England and Wales. The parties irrevocably agree that the courts of England and Wales shall have non-exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this Overarching Master Indemnity Agreement or its subject matter.

1.5 The Department of Health may terminate this Overarching Master Indemnity Agreement and remove the Supplier from the Master Indemnity Agreement Register at its convenience upon immediate written notice to the Supplier. For the avoidance of doubt, this will not affect any MIA Call-Off Agreements entered into by the Supplier and, subject to their terms, all such MIA Call-Off Agreements entered into by the Supplier shall remain in full force and effect notwithstanding the termination of this Overarching Master Indemnity Agreement.

1.6 The parties agree that a scanned or other form of electronic signature shall be a valid form of execution of this Overarching Master Indemnity Agreement, which shall commence and come into full force and effect from the date of signature of this Overarching Master Indemnity Agreement by the Department of Health.

SIGNED on behalf of the Supplier:	
Name and position:	
Date:	
SIGNED on behalf of the Department of Health:	
Name and position:	
Date:	

MIA CALL-OFF AGREEMENT

Note: An Authority should not enter into an MIA Call-Off Agreement unless either:

(i) There is a current Overarching Master Indemnity Agreement with current insurance in place, as evidenced by the fact that the Supplier is on Master Indemnity Agreement Register with current insurance that can be viewed at: <https://www.gov.uk/government/publications/master-indemnity-agreement-mia>; or

(ii) In exceptional circumstances for reasons of urgency where it is not possible for the Supplier to enter into an Overarching Master Indemnity Agreement prior to the delivery of the Equipment or where the insurance is not current and where the Authority itself has carried out its own checks and confirmed that the Supplier has appropriate current public liability and product liability insurance in place in respect of public liability and product liability covering the Equipment with the minimum cover per claim of five million pounds (GBP) (£5,000,000) in accordance with the requirements of the Master Indemnity Agreement Terms and Conditions (August 2016)

Company Name: ("Supplier")			
Address:			Postcode:
Contact Name:			
Contact E-Mail:			
Telephone No.:			
Company Registration Number (i.e. the registration number of the Company at Companies House or other relevant national companies registry):			
Is there an Overarching Master Indemnity Agreement in place with current insurance? If yes, state "Yes" and insert the MIA number here. If not, state "No":			
This box only requires completing where there is no Overarching Master Indemnity Agreement in place with current insurance. In these circumstances, the Authority should check that the insurance requirements have been met as per the note in red above and state "Insurances Checked by the Authority" here.			

Delivery Date:		(being the date of delivery of the Equipment to the Authority)	
Authority:			
Authority Address:			
		Postcode:	
Authority Contact Name:			
Authority Contact E-Mail:			
Authority Telephone No.:			
The Equipment to be supplied by the Supplier to the Authority			
Type of Equipment and its purpose:			
Model/Make:			
Serial Nos.:			
Value:			
Loan or transfer?: Note. Where disposable Equipment is provided, this should be on a transfer basis.			
Purpose of loan or transfer:			

Loan Period (to be completed only where the Equipment is be loaned):

[days/months/years (delete as appropriate)] commencing on [] day of []
 20[]

Premises and Location(s) at which the Equipment will be kept:

In consideration of the Authority taking the Equipment on a loan or transfer basis for the purposes outlined above and the mutual exchange of obligations under the Master Indemnity Agreement Terms and Conditions (August 2016), the Authority and the Supplier confirm that the Master Indemnity Agreement Terms and Conditions (August 2016) shall apply to the provision of the above Equipment by the Supplier to the Authority (on either a loan or transfer basis as specified above) and that upon signature of this MIA Call-Off Agreement by both the Authority and the Supplier a legally binding agreement on such terms shall come into full force and effect between the parties incorporating such Master Indemnity Agreement Terms and Conditions (August 2016), which shall be effective from the delivery date of the Equipment as set out above.

By signing this MIA Call-Off Agreement, the Supplier also confirms delivery of the Equipment detailed above to the Authority. By signing this MIA Call-Off Agreement, the Authority also acknowledges receipt of the Equipment detailed above on the delivery date referred to above.

SIGNED on behalf of the Supplier:

Name and position:

Date:

SIGNED on behalf of the Authority:

Name and position:

Date:

COLLECTION CONFIRMATION RECEIPT (for Equipment on loan only)**To be completed at the point the Equipment is collected by the Supplier.**

Without prejudice to the Authority's rights under this MIA Call-Off Agreement in relation to any outstanding obligations and/or liabilities of the Supplier, the Authority confirms collection by the Supplier, and the Supplier confirms receipt, of the Equipment detailed on the front page of this MIA Call-Off Agreement:

Date of Collection:	
SIGNED on behalf of the Authority:	
Name and position:	
Date:	
SIGNED on behalf of the Supplier:	
Name and position:	
Date:	

Record of Loan of Equipment to Patient/Carer from ward, service area or store

Supplying Ward, department or Store	
D.E.C. Department Equipment Controller	

Type of Equipment	
Make	
Model	
Asset Number	
Serial Number	

	Yes	No	N/A
PPQ (pre purchase questionnaire) completed if required	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Training provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Written instruction supplied	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Consumables supplied	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Spares/Accessories (eg cables) supplied	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments

Signed: _____ **on behalf of Trust**
Position _____
Date of issue _____
Intended Date of return: _____

Signed _____ **Recipient**
Address _____

Signed: _____ **on behalf of Trust**
Actual Date of return: _____

Equipment Training and Familiarisation Schedule

Staff using medical devices should be adequately trained so that they feel competent and confident to operate it. This includes clinical and non-clinical staff e.g. community loan stores, Sterile Services.

The training and familiarisation programme should be given by a person who is competent to do so, and address all issues relevant to the checking, operation and maintenance of the device. This should preferably be given by a validated trainer from the supplier/manufacturer.

A competent user should be familiar with the following aspects of the device, where applicable.

1. Why the device is used and what the device is intended for
2. What the device can be reasonably expected to do and how the device operates
3. How the device should be set up (including assembly/disassembly)
4. What disposables or accessories can be used with the device
5. The user protocols, operation and interpretation
6. The safety features and the need for them
7. How to set and deal with alarms appropriately
8. How to identify genuine and spurious alarms
9. How to recognise likely causes of failure including common mistakes in the operation of the device
10. How to recognise when the device has or might have failed
11. How to access and consult the user manual
12. How to clean/decontaminate/disassemble the device between patient episodes
13. What to do when in difficulty
14. How to identify an adverse incidents involving the device and how to deal with it
15. Any other issues of note as deemed appropriate by the trainer or service area manager

Medical Device Training Record – personal record

Name	
Grade	
Directorate	
Location	
Dept Equip Controller	

Device type	
Make	
Model	

Supplier name	
Address	
Trainer	

The following person have been given training in the operation of the listed above as per the **Equipment Training and Familiarisation Schedule (MD form 7)**

Name (PRINT)	Signature

Comments

Date of initial training _____

Competency Statement completed if required?

Date achieved: _____

Date of refresher training completed: _____

Belfast Health & Social Care Trust

DECONTAMINATION OF HEALTH CARE EQUIPMENT PRIOR TO INVESTIGATION, SERVICE OR REPAIR

INTRODUCTION

Manufacturers have informed the DHSS that current recommendations on decontamination of equipment are not being followed and that their staff are still being asked to handle dirty and blood stained items. In view of this the DHSS issued guidelines on the procedures which should be followed to prevent transmission of infection by contaminated equipment to all Trust Hospitals. These current recommendations require the issue of a certificate/statement of decontamination prior to submitting the equipment for servicing. Manufacturers have reported that this recommendation is rarely implemented.

Many manufacturers have indicated that they will instruct their staff to refuse to service or repair equipment that could be contaminated.

The Trust considers that anyone who inspects, services or repairs medical, dental or laboratory equipment, either on the Trust's premises or elsewhere, has a right to expect that articles have been cleaned and properly treated so as to remove or minimise the risk of infection. Equipment should never be presented or sent for service in a soiled condition.

LEGAL REQUIREMENTS - (Health & Safety at Work (NI) Order 1978)

1. Manufacturers are required to ensure that employees are not put at risk.
2. The DHSS, Area Boards, and Trusts have a similar duty towards their employees and also to those not in their employment, equipment manufacturers staff etc.

GENERAL CONSIDERATIONS FOR DECONTAMINATION

Equipment and articles that have been contaminated by contact with blood, other body fluids, pathological specimens or exposure to patients in isolation will require decontamination prior to examination by third parties. Third parties include hospital engineering staff, manufacturers' employees, and others who perform inspection and service, for example, at the Medical Defect Centre, Stony Road, Dundonald.

Equipment that is visibly soiled must never be presented or sent to third parties for inspection, maintenance or repair. If it cannot be cleaned or disinfected, it should be double bagged in clear plastic bags and labelled appropriately.

DECONTAMINATION METHODS - See Decontamination Policies

Only general advice, which must be interpreted in the light of local conditions, can be given here. Methods of decontamination which may be appropriate include:-

- (a) Steam sterilisation (134⁰ -137⁰ C for 3 - 3 ½ minutes)
- (b) Low temperature steam (71 - 75⁰C for at least 10 minutes)
- (c) Dry heat (e.g. 160⁰ C for 120 minutes)
- (d) Chemical methods including peracetic acid and chlorine releasing agents.
- (e) For surface contamination cleaning including liberal swabbing with water at about 60⁰C containing detergent may be appropriate. N.B. Water at 60⁰ C causes scalding.

In cases of doubt about the appropriate method, advice should be sought from:-

- (a) The Manufacturer or Agent
- (b) CDU (Central Decontamination Unit).
- (c) Decontamination Manager
- (d) Infection Prevention Control department.
- (e) Consultant Microbiologist/Deputy
- (f) Medical Physics or Biomedical Engineering Staff..

DOCUMENTATION

1. A written certificate/statement that decontamination has been carried out should be provided. If the equipment is to leave the premises, the certificate/statement should be enclosed in an envelope affixed to the outside of the package, envelope should be marked: **"Examine enclosed documents before unpacking"**. A copy of the certificate to be used is attached; this should be photocopied for stock supply.
2. Decontamination procedures should be undertaken by suitably qualified, trained and supervised staff using agreed methods and equipment. It may be appropriate to record decontamination procedures in the equipment's log book.
3. Duplicate copies of the certificate should be retained by the department manager.
4. Supplies of blank certificates should be generated by photocopying.



Declaration of Contamination Status (Decontamination certificate)

From (consignor): _____
 Address _____
 Reference _____
 Emergency Tel _____

To (consignee): _____
 Address _____
 Reference _____

Type of equipment _____ Manufacturer _____
 Description of equipment _____
 Other identifying marks _____
 Model No _____ Serial No _____
 Fault _____

Is the item contaminated? Yes* No Don't know

*State type of contamination: blood, body fluids, respired gases, pathological samples, chemicals (including cytotoxic drugs), radioactive material, or any other hazard:

Has the item been decontaminated? Yes No Don't know

◇ What method of decontamination has been used? Please provide details

Cleaning _____

Disinfection _____

Sterilisation _____

◆ Please explain why the item has not been decontaminated:

Contaminated items should not be returned without prior agreement of the recipient and must not be sent by post.

This item has been prepared to ensure safe handling and transportation:

- Double package in suitable and robust packing to allow safe transport and ensure outer packaging is not contaminated or breached.
- Recipient is aware of contamination status prior to transport
- Clearly labelled with decontamination status.

Name (printed)

Signature

Position

Date

Tel

Condemnation & Disposal Record

Quantity	Description of asset	Serial number	Asset number	Reason for condemnation

Method of disposal _____

The above equipment has been Inspected and condemned

Requested by	Verified by
Name	Name
Position	Position
Signature	Signature
Date	Date

Checklist for Sale or Transfer of Ownership of a Used Medical Device

(based on appendix 1, DB9904(NI) supplement 1, 2002)

If selling or transferring the used medical device to a new owner, an information package should be provided including:

	Yes	No	N/A
Decontamination certificate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Service history	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Quality assurance tests or performance tests eg: PAT/ electrical safety test, battery condition (DB9805)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
User manual	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Training requirements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Service manual	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Service history	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Usage logbook	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unique identifier	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If selling for export or donating to charities abroad consider:

	Yes	No	N/A
Is an export certificate required?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Whether any foreign regulations apply?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the medical device comply with regional regulations?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are there any special requirements for transport abroad?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If disposing consider:

	Yes	No	N/A
Is decommissioning of the medical device required?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has the medical device been adequately disabled?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are any disposal regulations applicable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments

After completing this checklist, a risk assessment should be completed to establish safety and liability issues regarding the sale or transfer of the product

IN ALL CASES ANY PATIENT INFORMATION STORED ON THE EQUIPMENT MUST BE REMOVED PRIOR TO SALE, TRANSFER OR DISPOSAL



DISPOSAL OF EQUIPMENT SURPLUS TO REQUIREMENT

The following goods, which are surplus to Trust requirements, have been redistributed/donated as detailed below:

Description of goods:

Distributed to:

(in the event of a charitable donation a request on the organisation's headed paper should be attached)

The recipient should retain one copy of this form as proof of approved donation.

A second copy should be returned to the Supplies Dept.

Signed: _____ on behalf of Trust

Position _____

Date _____

PLEASE NOTE: The buyer accepts full responsibility for ensuring this equipment is in safe working order before use, or in the event of disposal meets all current environmental regulations. The buyer absolves Belfast Healthcare Trust from all liability in respect of damage / injury to any persons or property

Signed _____ (Recipient)

Address _____

Date: _____

NIAIC ADVERSE INCIDENT REPORT FORM

Details of the report:	Location of the incident:
Reporting Body: Address: Post Code : Reporter : Position : Tel No : Email : Belfast Trust IR1 Reference:	As Reporter : <input type="checkbox"/> Facility/Building: Ward/Dept : Local Contact : Position : Tel No : Email :

Details of device:			
Product		Catalogue No	
Model		Serial No	
Manufacturer			
Supplier			
Batch No		Expiry date	
Date of mfr		Quantity defective	
Location of device now			
Is there a CE-mark? Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/>		If YES, was the manufacturer or supplier contacted? Yes <input type="checkbox"/> No <input type="checkbox"/>	

Incident Details : Date of Incident _____
Nature of Injury : Fatality <input type="checkbox"/> Serious <input type="checkbox"/> Revision <input type="checkbox"/> Distress <input type="checkbox"/> Minor <input type="checkbox"/> None <input type="checkbox"/>
Injury details:
Nature of defect / details of incident:
Action taken by staff :
PLEASE NOTE IT IS ILLEGAL TO SEND CONTAMINATED ITEMS THROUGH THE POST. If you still have the incident device please retain it and await further instructions from the NIAIC.
Signed _____ Date _____

Please send completed form to:

Preferred method e-mail : niaic@dhsspsni.gov.uk Send copies to the Trust Medical Devices Manager & Medical Devices Coordinator	Postal Address Northern Ireland Adverse Incident Centre (NIAIC), Safety Strategy Unit, CMO Group, Department of Health, Room D1, Castle Buildings, Stormont Estate, Dundonald, Belfast, BT4 3SQ, [REDACTED]
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Useful Contacts

NB this list is not intended to be exhaustive and you can check for specific contact details and updates at the contact page on the Medical Devices webpage on the Trust Hub

- Medical Devices team, corporate governance
 - Medical Devices Manager – 028 950 48894
 - Medical Devices Coordinator – 028 950 48840
- Estates
 - Asset registration - 02895049128
 - Medical engineering - 02895048670
 - Service contracts

Title	Telephone No
Divisional Manager Contracts	02895048954
Contracts Officer	02895046971
Contracts Officer	02895047313
Contracts Officer	02895044144
Contracts Officer	02895045613

- Capital Asset finance - 02895046051
- Medical devices management system / AIMS, - 02890633371
(medical physics)
- LABS POCT (Point of Care Testing) - 02890633007
- ICT
 - Governance -
 - Helpdesk - 08005873878
- Medical physics - 02890633840
- Clinical engineering – 02895048747
- Waste management - 02895047293

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Revised Public Procurement Policy for the Public Sector ref HSS (PPM) 8/2003

Medical Device Training Criteria (2008) THOTH

Belfast Trust Policies

Adverse Incident Reporting and Management Policy

Asset Disposal Policy (TP070/11)

Data Access Agreement

Decontamination of Reusable Invasive Medical Devices (SG028/08)

Decontamination of Endoscopes, TOE probes and related equipment (TP058/09)

Management of Patient Controlled Analgesia in Adult Patients (CG0030/08)

Medical Devices Policy v5, 2017 (TPO16/08)

Point of Care Testing Policy v2 (SG 38/11)

Research Guidance - How to submit a clinical investigation application for a non CE marked device or a CE marked device for a new purpose (BHSCT/RG/SOP 017)

Roles & Responsibilities of Staff in relation to environmental cleanliness and cleanliness of equipment (2009), v2