



Western Health  
and Social Care Trust

## **Policy for the Management of Medical Devices**

Date:- July 2009

Review Date:- July 2011

<b>Title</b>	<b>Policy for the Management of Medical Devices</b>
<b>Reference Number</b>	<b>Corp09/14</b>
<b>Implementation Date</b>	<b>July 2009</b>
<b>Review Date</b>	<b>July 2011</b>
<b>Responsible Officer</b>	<b>Director of Primary Care &amp; Older People</b>

## Contents

- 1 INTRODUCTION**
  - 1.1 Management Structure
  - 1.2 Medical Devices & Decontamination Working-Group
  - 1.3 Responsibility for Medical Devices
  
- 2 PROCUREMENT**
  - 2.1 Business Case Proforma Completion
  - 2.2 Ordering Equipment
  
- 3 PUTTING INTO SERVICE**
  - 3.1 Delivery
  - 3.2 Acceptance Testing
  - 3.3 Installation and Release of New Devices
  - 3.4 Medical Device Acceptance Form
  - 3.5 Equipment Registration
  - 3.6 Storage of New Devices
  - 3.7 Prescription of Medical Devices
  - 3.8 Medical Devices on Trial, Loan or Rent
  - 3.9 Medical Devices on Loan to Patients
  - 3.10 Medical Device Modification
  - 3.11 Medical Device Vigilance
    - 3.11.1 Medical Device Adverse Incident Reporting
  
- 4 TRAINING**
  - 4.1 Staff
  - 4.2 Instructions of Use
  - 4.3 Maintaining Records of Training
  
- 5 MEDICAL DEVICE/EQUIPMENT MAINTENANCE**
  - 5.1 Routine Maintenance
  - 5.2 Planned and Breakdown Servicing
  - 5.3 Guidelines on Decontamination
  
- 6 MEDICAL DEVICE REPLACEMENT**
  
- 7 TRANSFER AND DISPOSAL OF USED MEDICAL DEVICES**
  - 7.1 Single Use Devices
  - 7.2 Condemning
  - 7.3 Decommissioning

- 7.4 Disposal
- 7.5 Transfer of Old or Obsolete Equipment

## **8 APPENDIX A**

- 8.1 Medical Devices in Practice

## **9 APPENDIX B**

- 9.0 Accountability Arrangements for Integrated Governance

### **APPENDIX C**

- 9.1 Roles & Responsibilities
  - 9.1.1 Chief Executive
  - 9.1.2 Director of Corporate Planning & Performance Management
  - 9.1.3 Directors with Nominated Responsibility for Controls Assurance Standards
  - 9.1.4 Medical Devices & Decontamination Working-Group
  - 9.1.5 Assistant Directors
  - 9.1.6 Professional Staff
  - 9.1.7 Departmental Equipment Controllers
  - 9.1.8 Medical Engineering Manager/Technical Co-Ordinator (Estate Services)
  - 9.1.9 End User
  - 9.1.10 Regional Supplies Services
  - 9.1.11 Community Appliance Stores

## **10 APPENDIX D**

- 10.1 Business Case Approval Process

## **11 APPENDIX E**

- 11.1 Medical Devices Acceptance Form
- 11.2 NIAIC Adverse Incident Report Form

## **12 APPENDIX F**

- 12.1 Devices on Loan Form

## **13 APPENDIX G**

- 13.1 Medical Device on Loan Form to Patients

## **14 APPENDIX H**

- 14.1 Declaration of Decontamination Certificate

## **15 APPENDIX I**

- 15.1 Medical Device Equipment Alert Management Process

## **16 EQUALITY & HUMAN RIGHTS STATEMENT**

## 1.0 INTRODUCTION

This policy document outlines the Western Health and Social Care Trust's responsibilities in ensuring the effective management and decontamination of medical devices as detailed within "Medical Device and Equipment Management for Hospital and Community Based Organisations" DB9904, and all subsequent guidelines. The objective of policy is to minimise the risk to both patients and users of medical devices by identifying the hazards and eliminating the risks. Where risks cannot be eliminated they must be reduced to a minimum. Residual risk must be assessed and control measures identified.

The policy will outline the systems and processes that the Trust requires to have in place to ensure the effective management of medical devices through all stages of the process from justification of need, identifying funding, procurement, introduction into service, maintenance, training and the maintenance of training records, decontamination, being condemned, replacement and ultimate disposal.

### Definition of Medical Device

The European Directive on Medical Devices, defines a Medical Device as:

An instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which -

1. Is intended by the manufacturer to be used for human beings for the purpose of -
  - Diagnosis, prevention, monitoring, treatment or alleviation of disease,
  - Diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or handicap,
  - Investigation, replacement or modification of the anatomy or of a physiological process,
  - Control of conception;
2. It 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. Examples of common categories of medical devices are presented in Appendix A.

### **1.1 Management Structure**

The Trust has a responsibility to ensure that an effective medical device management structure is put in place. The organisational arrangements for integrated governance are presented at Appendix C which illustrates the Medical Devices & Decontamination Working Group within the Trust's Risk Management & Sub Committee (attached at Appendix C) show how this will be achieved for medical device management and decontamination within the Trust.

***See Appendix C for organisational arrangements***

## **1.2 Medical Devices & Decontamination Working Group**

The Medical Devices & Decontamination Working Group will ensure that effective systems are in place to manage medical devices including both equipment and consumables. Specialist advisors will be co-opted to the membership of the working group when required.

The Group will advise the Trust on establishing a more effective approach to the purchase of medical devices, monitor and make recommendations for capital purchases and emerging new technology. The group will strive to improve the co-ordination between procurement, business planning, maintenance, risk management and training.

These include, where appropriate: -

- Technical specifications
- Financial data
- Value for money
- Regulatory compliance information
- Decontamination issues
- Device/equipment evaluation reports
- User experience and preferences
- Comparing costs and features of alternative devices
- Standardising on a single model where possible or rationalise to the lowest possible number
- Maintenance and training implications
- Advise and support users, make recommendations where appropriate
- Provide feedback to groups as necessary

## **1.3 Responsibility for Medical Devices**

The Assistant Directors will assume overall responsibility for ensuring that this policy is implemented in relation to the management and decontamination of medical devices within their respective Divisions/Directorates. Management responsibility extends through all stages of the process from procurement to replacement and ultimate disposal, including training, infection control issues, and maintenance. This responsibility also covers health and safety matters related to medical devices. Accurate records must be maintained detailing all the activities and inputs relating to medical devices. Where devices are in common use throughout the Trust, every effort must be made to standardise such devices, and where possible maintenance should be co-ordinated on a Trust-wide basis. Directorates are required to liaise with the Medical Devices and Decontamination Working Group to ensure that these medical device needs are met.

Within each Department there will be a designated Departmental Equipment Controller (DEC), who has day to day responsibility for the equipment, maintaining an inventory of the equipment and liaising with the 'Medical Engineering Manager'/Technical Co-Ordinator' on all matters relating to the technical management of the equipment. Directorates must ensure that these responsibilities are met, either through Ward Manager/Heads of Department/Locality Managers or through the provision of technical and professional support outside of the Directorate.

A broader range of roles and responsibilities for these functions are set out in **Appendix B**.

## 2.0 PROCUREMENT

The procurement of all medical devices must be in accordance with the Trust's procedures and follow the Department's guidance (PPM) 8/2003; to ensure that this process incorporates appropriate professional expertise. The circular (PPM) 8/2003 implements the N.I. Public Procurement Policy and states that Health and Social Care Services are required to use Centres of Procurement Expertise for all procurement activity. These include Regional Supplies Service and Health Estates Department (estates contracts exceeding £500k only). Procurement of medical devices must also comply with all relevant UK Public Supply, Services and Works contracts legislation and DHSSPS Mini-code value for money guidance.

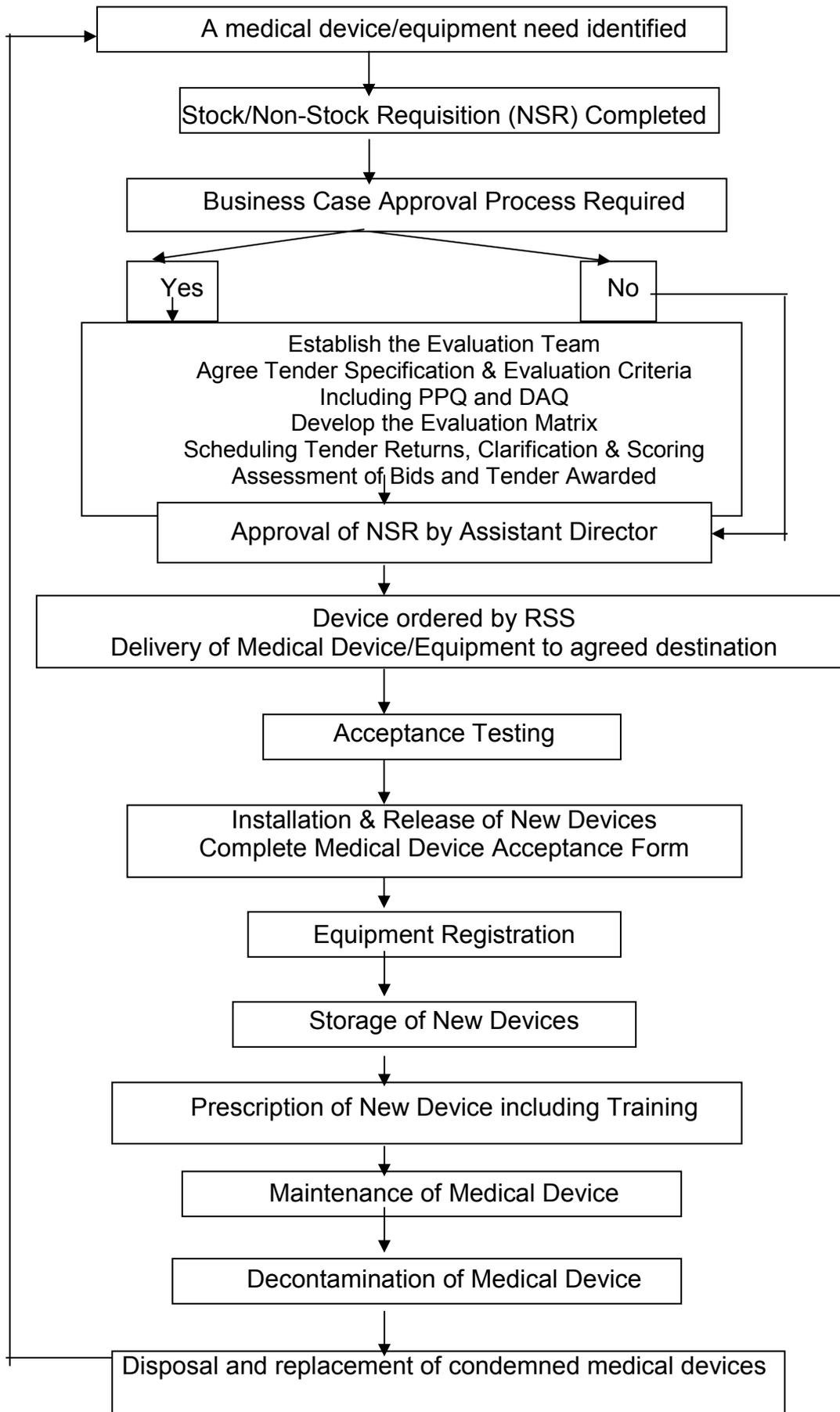
Purchasing of medical devices has become more complex involving decisions on the direct replacement, acquiring a new model or specific type of device. In each case it is important to consider all costs incurred through the decision to purchase a specific device prior to the approval of capital purchases. These costs include the capital, installation and revenue costs, including maintenance and consumable costs across the life of the medical device, training, replacement and ultimate disposal. A Business Case and a Technical Specification should be prepared prior to approval, and funding secured for capital purchases. This should include any building or engineering services required for the safe accommodation and installation of the medical device.

Technical compatibility with existing medical devices and equipment needs to be assessed prior to purchase. Directorates must select from the Trust's standardised list of devices. If device selection includes non-standard devices then a user evaluation programme should be considered. An aim of the Medical Devices and Decontamination Working Group is to rationalise the number of different models of medical devices in use within a Department, where possible. This will avoid confusion, reduce risk, and reduce the amount of staff training required. The Medical Engineering Manager/Technical Co-ordinator's and Departmental Equipment Controller's are responsible for ensuring that the Trust's procedures for installation and commissioning are carried out. The Trust's Purchasing Procurement Procedure is presented as a flowchart overleaf.

### Medical Devices on Lease or Loan

When a medical device is obtained under lease or loan arrangements and remains under commercial ownership as in public private partnership, there is still a requirement under duty of care and contractual obligations to manage it. In relation to commercially owned equipment, Directorates need to secure consent from the respective owner that equipment information will be held on Trust databases for the purposes of managing it. Individuals or organisations wishing to donate medical devices must be made aware of the Trust's procurement policy and procedures for managing medical devices. Directorates should give advice on selecting appropriate devices taking into account the Trust's standardised list of devices. Donated devices without CE marking must not be accepted into service.

**Purchasing Procurement Procedure**



## 2.1 Business Case Proforma Completion

The Western Trust has in place a process to ensure that any request to support the purchase capital equipment is supported by the required documentation to provide assurance to the Corporate Management Team and to allow decisions to be made.

A business case proforma must be completed for each new request and submitted to the Assistant Director of Corporate Planning. A copy of the Business Case Proforma is attached at Appendix D for information. This will provide high level information to allow further decision to be made. The proforma will be returned if it has not been signed off by the relevant Director and prioritised across the directorate priorities prior to submission. It will then be subjected to the scrutiny of the case review team and submitted to CMT. This review meeting takes place monthly.

There is a recognition that there may be occasions when a more timely response may be required, if there is a risk of adverse impact on service delivery. If this is the case then the Directorate's Business Support Officer should contact the Assistant Director of Corporate Planning and seek assistance in expediting the process.

### Devices valued greater than £5000

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. A business case must be prepared for these purchases. The scope of the Business Case is proportionate to the scale of investment in accordance with DHSSPS guidelines.

#### *Business Case*

This should examine

- The object of the investment
- The options associated with the investments i.e. do nothing, repair/modify, replace, buy service from elsewhere
- Evaluate the costs (whole of life) and benefits including technical/operational aspects of each option
- Assess training needs.
- Recommendation of way forward

All devices purchased must follow the normal procurement procedure, with the requisition prepared by the directorate and properly authorised as per the Trusts' Scheme of Delegation and Schedule of Delegated Authority.

Prior to the procurement of any medical device (**including medical devices on loan, trial or rent see 3.8**) a Decontamination Assessment Questionnaire (DAQ) (where applicable) plus a Pre-Purchase Questionnaire (PPQ) form must be issued by Regional Supplies Service. The information contained on these forms must be checked and approved by the Procurement Working Group.

**Assessment must also be made of**

- Maintenance implications, including staff and equipment costs
- Compatibility with existing equipment
- Specific requirements for installation
- Training requirements
- Cleaning/Decontamination
- PPQ Forms

**2.2 Ordering**

PPQ forms must be sent to the suppliers when quotations or tenders are invited. The Trust's (or RSS) official order form can be used. The Departmental Equipment Controller must liaise with the Trust Medical Engineering Manager/Technical Co-Ordinator, Estates Services Department and HSDU regarding:

- Installation of the device.
- Supply of appropriate instructions for the safe and effective use of the device.
- Supply of recommended decontamination instructions.
- Access to manufacturers' guidance on maintenance as required by in-house technical servicing.
- Training
- Appropriate testing and validation certificates to be supplied with the device.

**3.0 PUTTING INTO SERVICE**

When devices are first delivered to the Trust it is essential that acceptance checks are carried out prior to use by professional staff and the end users. These checks aim to identify faulty or damaged products. Manufacturers' acceptance checks may include simple visual checks and functional checks by professional user or end-user and calibration and safety tests by specially trained staff.

Community

For community medical devices suitable acceptance checks will be carried out by the Community Appliance Staff. Where necessary functional checks will be carried out by the Professional Users.

**3.1 Delivery**

Delivery of medical devices must be to a point advised by the Medical Engineering Manager/Technical Co-Ordinator or estates personnel on the requisition. 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.

- Inform the technical co-ordinator, in writing, of delivery.
- Sign off appropriate documentation.
- Estates Acceptance Form

The Medical Engineering Manager will decide whether the device is then transferred to the end users department after an acceptance test has been conducted.

### **3.2 Acceptance Testing**

The Medical Engineering Manager/Technical Co-Ordinator or deputy must ensure the following checks are carried out prior to use by the end user.

- Check delivery documentation to ensure validity of the medical device.
- Acceptance checks including the recommended manufacturer tests are performed to ensure that the device meets the correct performance and safety standards.
- Inform the Department/Directorate Manager/Regional Supplies Service that the device is formally accepted so that payment can be made.

### **3.3 Installation and Release of New Devices**

The Medical Engineering Manager/Medical Devices Co-Ordinator/Technical Co-Ordinator or deputy is responsible for:

- Ensuring any other required services are satisfactory and meet requirements.
- Ensuring that the device, if required, is tested for electrical safety prior to installation.
- That suitable arrangements have been made for maintenance, training, cleaning and decontamination.
- That the device has been marked with the Trust's asset number and entered on the Trust database.

### **3.4 Medical Device Acceptance Form**

A **Medical Device Acceptance Form (Appendix E)** must be completed for all new devices including devices under Trust and Commercial ownership. The Medical Engineering Manager/Technical Co-ordinator or equipment controller is responsible for completing the form and returning it to Estates for equipment registration.

#### Community Service

Medical Devices Acceptance Forms must be completed and registered on the Community Devices Register (MEASALS) in Foyle and Community Stores in Tyrone & Fermanagh Hospital.

### **3.5 Equipment Registration**

The Trust is required to keep accurate and accessible records on its medical devices and equipment. All medical equipment must be uniquely identified by an asset number and its details as captured on the medical device acceptance form will be transferred on to the Trust's computerised equipment management system. Identifying the stock of medical devices and equipment currently available for use is important to the Trust but it is also essential that the Trust manages individual devices and equipment to:

- Ensure planned preventative maintenance and rapid repairs
- Log service histories and safety related issues for device review and training assistance.
- Generate management information in relation to running and replacement costs.

### **3.6 Storage of New Devices**

Ward Managers/Heads of Department/Locality Managers need to ensure where medical devices are stored within their department that the manufacturers instructions are adhered to. Inappropriate storage can affect their subsequent safe use. Manufacturer's information and instructions both on storage conditions and shelf life should be followed.

In particular Ward Managers/Heads of Department/Locality Managers 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 devices being stored for too long or shelf life of batteries and sterile products is not exceeded.

Note current arrangements

- Medical Equipment Library (Altnagelvin Hospital)
- Community Equipment Stores (Erne Hospital, Tyrone & Fermanagh Hospital & Gransha Hospital) pending the implementation of the Review of Community Equipment
- Sub stores in Community for emergency items
- All Health Centres have sub-stores for medical devices

### **3.7 Prescription of Medical Devices**

Directorates are responsible for ensuring that the prescribing of medical devices is performed by staff with appropriate professional qualifications and experience. The prescription is the responsibility of the prescribing professional. The Assistant Director for each service area must ensure that procedures are in place to ensure that suitably qualified and experienced staff undertake the prescription of medical devices.

### **3.8 Medical Devices on Trial, Loan or Rent**

A clear distinction must be made between medical devices on loan and medical devices on trial.

**A medical device on loan** is where a medical device is brought into the Trust as part of a current approved procedure to replace an existing medical device. An example is where equipment may be out of commission for repair or awaiting spare parts or where equipment has been condemned and a lengthy tendering process is required for its long-term replacement.

**A medical device on trial** is where a medical device is obtained for assessment prior to a commitment to purchase. In the majority of occasions this should only occur as part of the competitive tendering process. There may, however, be occasions where a trial takes place prior to tendering where the trial is designed to assess the need and assist in compiling a business case and/or specification of need.

The Trust must satisfy itself that all medical devices used on its premises or within the community, including devices on temporary loan, trial or rent are safe, are suitable for their intended purpose, and that arrangements for their use are satisfactory. It is also essential that prior to delivery of this type of Medical Device, the supplier completes the Trust's Indemnity Form (**Device on Loan Form – Appendix F**)

**Only Assistant Directors/Clinical Directors, or delegated officers**, may agree to a medical device being on loan or accepted for trial, and that it is suitable for its intended purpose. This must be done in conjunction with the Regional Supplies Service via a process duly authorised by the Assistant Director. It is recommended that the loan period is identified and limited to six months, with the possibility of renewing the period should the study require it.

Prior to any medical device coming on site for loan or trial, a Decontamination Assessment Questionnaire (DAQ) (where applicable), plus Pre-Purchase Questionnaire (PPQ) form must be obtained from the supplier(s). Regional Supplies Service will facilitate the issuing and return of these forms. The information contained on these forms must be checked and approved by HSDU, Estate Services, Risk Management, Infection Control and any other specialist advice sought as appropriate. Once approval has been received, Regional Supplies Service will issue an Indemnity Form to the Supplier(s) for completion and make arrangements for the equipment to come on site. The Regional Supplies Service will also request the Supplier(s) to make contact with HSDU, Estate Services or other specialist groups (if necessary) and appropriate wards/departments prior to the equipment coming on site. **Any medical device, which requires decontamination via HSDU, must arrive in HSDU at least 48 hours before intended use.**

The Ward Managers/Heads of Department/Locality Managers must

- Ensure that Estates Services Department/Technical Co-Ordinator is informed so that a Devices on Loan Form is satisfactorily completed and received prior to delivery of the medical device.
- Instruct the supplier to contact the Equipment Controller/Programme Manager at least 2 days prior to delivery.

- Be satisfied that proper arrangements have been made for its use, including training for staff and/or carers', following the Trust's policy guidance on the delivery of new devices and training requirements.

The Medical Engineering Manager/Technical Co-Ordinator must

- Consider whether the loan term period requires the medical device details to be placed on an appropriate inventory system for purposes of management. Ensure that the supplier agrees to such information being held on a Trust register and completes the necessary **Medical Device Acceptance Form** when the item is received.
- Ensure that the Devices on Loan Form has been received prior to delivery of the device.
- Check that the device is electrically safe
- That any environmental, safety or installation problems are discussed with the appropriate persons, including Estates Services staff
- Identify loan period and inform the supplier of the return of the device at the end of the period or request a renewal period.

### **Exclusions**

Prior completion of the **Device on Loan Form** does not apply to the demonstration of medical devices by representatives of firms to staff, provided:

- The firm's representative is present
- The device is not connected to a patient
- There is no radiation hazard (lasers, etc.) no services required (other than a 13 amp socket or piped medical gas) and no other special requirements.
- The piece of equipment is under a service contract and a (like for like) replacement is on loan from the company during repair.

### **3.9 Medical Devices on Loan to Patients/Carers**

Directorates issuing patients/carers with devices for use both within the Trust and outside should ensure that

- Patients/carers are trained in the safe and effective use of the medical device including, cleaning and decontamination of the medical device.
- Instructions given to patients/carers must be vetted for suitability by the prescribing professional in consultation with the supplier if required.
- Patients are made aware of the administrative and technical support and relevant contact numbers
- A record of the medical device on loan should be recorded on a computerised system to ensure return of equipment.
- Medical devices are collected after use by the Directorate representatives or organised through the commercial owner if required.

(See Appendix G – Medical Device on Loan Form to Patients)

### **3.10 Medical Device Modification**

Medical Devices should not be modified, nor used for purposes not intended by the manufacturer.

### **3.11 Medical Device Vigilance**

The Trust is required to have in place proper procedures that will enable the reporting of adverse incidents and dissemination of safety related documents. The Assistant Director shall ensure that the Trust's procedures for reporting adverse incidents are followed and that safety related information are disseminated to the appropriate personnel and acted upon where necessary.

#### **3.11.1 Medical Device Adverse Incident Reporting**

All adverse incidents associated with medical devices must be reported on the NIAIC ADVERSE INCIDENT REPORT FORM (A1 Form). Further reporting of incidents involving medical devices will be co-ordinated through the Trust's nominated liaison officer/Medical Engineering Manager to N.I. Adverse Incident Centre (NIAIC). Key procedural points are as follows:

- Adverse incidents, reactions and defective products are reported promptly
- All incidents involving medical devices must be reported in the first instance via the Trust's *Incident Reporting Form* (Appendix E) followed by the completion and submission of Adverse Incident form A1 to NIAIC and copied to the Medical Engineering Manager/Trust's Liaison Officer.
- Serious cases should be reported to NIAIC by the fastest means available.
- Devices/equipment or plant involved in an adverse incident together with other material evidence (e.g. packaging of a single use device, giving sets used with infusion pumps etc.) should be clearly identified and kept in quarantine, where appropriate, until NIAIC's investigating officers have been consulted.
- 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,
- Local action is taken as necessary to ensure the safety of patients, staff and clients.
- Guidance should also be sought by referring to the Trust's Creutzfeldt–Jakob Disease (CJD) policy.

Trust staff, including those in the contracted sector, at all levels, should be aware of their responsibilities, and of the procedures to be used with regard to reporting and the isolation and retention of defective items.

### **3.12 MDEA Alert Management**

The Trust has a responsibility to respond to MDEC Alerts issued by NIAC within the specified timeframes. A Medical Device Equipment Alert management process has been implemented by the Trust and staff are expected to comply with this procedure. A Flow Chart illustrating the Trust procedure is attached at Appendix I.

## 4.0 TRAINING

The Ward Managers/Heads of Department/Locality Managers together with Departmental Equipment Controllers are responsible for ensuring that staff are trained in the safe use of medical devices. All new staff, as part of their induction, must be made aware of the procedures relating to any medical device that they may be required to use. Where specific training is required then this must be arranged as part of the induction process.

Resources and time must be allocated to training in order to:

- Ensure patient safety and minimise adverse incidents
- Ensure the appropriate device is used with each therapy;
- To ensure that staff are confident and competent in the effective use of medical devices for the safety of patients;
- Report any adverse incidents;
- Keep up with technological developments

Training programmes should be:

- Multi-disciplinary - where appropriate
- Included in staff induction programmes
- Designed to include assessment of practical competence in specific devices
- Recorded/Documented
- Form part of continuous professional development
- Reviewed to reflect changes in equipment or software
- Include correct decontamination procedures
- Evaluated and updated as necessary

Training is a key element in device safety. Professional users are responsible to ensure that training needs cover:

- Correct choice of device
- Setting up of device
- Proper use of device including any necessary cleaning/decontamination
- Identify and correct malfunctions

Where a new device is being introduced into a Directorate then training requirements must be identified and the appropriate training made available as part of the commissioning process. The Departmental Manager/Departmental Equipment Controller must also ensure that on-going training is provided for the lifetime of the device. This can be provided by the supplier or in-house as appropriate. Records must be kept of all training carried out within the Directorate and record on the Trust's approved training administration system.

### 4.1 *Professional Staff*

When organising training for new models of a familiar device professional users need to know

- How the operator's manual is organised

- How any controls and adjustments work
- Be aware of potential errors arising from misleading similarities to existing devices.

#### **4.2 *Instructions for Use***

Ward Managers/Heads of Department/Locality Managers are responsible for ensuring that professional users and carers have access to manufacturer's instructions. Where appropriate they should ensure that

- Users sign statements to the effect that they have received instruction on the safe use of devices or equipment
- Revised manufacturer's instructions are managed and instructions for use disseminated to all users.
- All other instructions are evaluated for adequacy.

#### **4.3 *Maintaining Records of Training***

Ward Managers/Heads of Department/Locality Managers are responsible for maintaining accurate records of staff training and where appropriate, competence assessments in the operation of all medical devices used in care delivery.

### **5.0 *MEDICAL DEVICE/EQUIPMENT MAINTENANCE***

Keeping medical devices safe and effective requires both routine maintenance procedures supervised by professional users, and planned preventative maintenance carried out by suitably trained technicians or specialist contractors.

#### **5.1 *Routine Maintenance***

Professional users and end-users are responsible for ensuring that routine maintenance is carried out including - regular cleaning, preparation for use, and checking of devices. Cleaning and decontamination have safety implications. Refer to Trust's policy document on Disinfection and Decontamination Guidelines for further guidance.

#### **5.2 *Planned and Breakdown Servicing***

Planned preventative maintenance should follow manufacturer's guidance on procedures and staff training. Devices, requiring maintenance must be cleaned and, where relevant, decontaminated before release. Refer to Trust's policy document on Disinfection and Decontamination Guidelines for further guidance.

Breakdowns can be dealt with either by substituting an equivalent device, or by rapid repair. In both cases planning is needed - to be sure that suitable replacement devices

are available in the first case, and that maintenance contracts provide for adequately short downtimes.

The Medical Engineering Manager/Departmental Equipment Controller will co-ordinate and manage the maintenance and servicing of all devices. Estates Services Department must be notified of such arrangements. All electromedical devices are required to be periodically safety tested. A certificate of decontamination must be completed where necessary.

### **5.3 Guidelines on Decontamination**

Head of Pharmacy and Medicines Management has responsibility for Decontamination Controls Assurance Standards.

There are two categories of guidelines on decontamination – generic which is relevant across the Trust and departmental specific:

The generic guidelines are contained within the Trust's infection control manual and are pertinent to all staff using general medical devices i.e. beds. These specific decontamination guidelines will be regularly updated with expert advice from the Infection Control Manager

Other guidelines are specific to particular departments such as HSDU and Endoscopy. These specific decontamination guidelines will be held by the individual departments and will be regularly updated with expert advice from the Decontamination Manager.

Decontamination of Equipment within the Trust is the responsibility of all staff who use equipment as laid out in Trust Decontamination Arrangements.

Medical devices and equipment to be inspected, serviced or repaired should be in a condition which is safe for all personnel who may come into contact with them during transit and subsequent handling. The device should not only be mechanically and electrically safe, but also carry a limited risk of infection. Guidance on Decontamination of medical devices before repair can be found in section 9 of the Trust Infection Control manual. This includes the requirement to complete a certificate of decontamination. (Appendix H).

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.

#### *Devices used by high –risk patients:*

It is the responsibility of the user (ward staff etc.) to ensure that any device used by an infected or potentially infected patient including those suspected of having hepatitis-B, AIDS or other Hazard Group 3 pathogens which requires servicing or repair is fully decontaminated or that full instructions are given as to the precautions to be taken by staff handling the device.

#### *Devices returned to Manufacturers:*

Estate Services Department is responsible for returning all devices to the manufacturer for repair.

- 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 declaration of decontamination certificate must be issued. (Appendix H)
- Where appropriate a purchase order should be included with the returned item.

## 6.0 MEDICAL DEVICE REPLACEMENT

The Trust has a responsibility to ensure that there is a planned programme for the replacement of medical devices that are commonly used in all service areas. The Medical Devices Management and Decontamination Working Group will be responsible for identifying the need for replacement programmes for commonly used equipment. Examples include bed frames and static mattresses. There is a need for close liaison between The Procurement Group and Capital Planning Department. Directorates need to plan for the replacement of medical devices. To assist in this assessment, certain criteria should be considered as to whether the device is no longer serviceable:

- Worn out beyond economic repair
- Damaged beyond economic repair
- Unreliable
- Clinically or technically obsolete
- Spare parts no longer available
- More cost-effective or clinically effective devices have become available
- Unable to be cleaned effectively prior to disinfection and/or sterilisation.

If any of the above criteria applies then the device must be considered for replacement. Should the device pass these criteria then a date should be set for re-testing, preferably in one year's time.

(Refer to Section 2 – Purchasing Procurement Procedure Flowchart)

## 7.0 TRANSFER and DISPOSAL of USED MEDICAL DEVICES

### 7.1 *Single Use Devices*

Single use medical devices must be fit for their intended purpose and **not be reprocessed for reuse.**

### 7.2 *Condemning*

When a medical device is required to be condemned the respective department must notify the Estates Department so that the asset register can be updated with all relevant details.

### Community Equipment

The Community Appliance Store staff will arrange for disposal and removal from the computerised database (MEASALS), Foyle area. In the Southern Sector the Community Stores at Tyrone & Fermanagh Hospital will remove items for disposal from the database.

### **7.3 Decommissioning**

Any medical device deemed not reusable should be decommissioned. This requires the device to be decontaminated, made safe and made unusable so that an inappropriate person does not use the medical device and expose themselves to potential hazards. This process should be managed with the Medical Engineering Manager/Technical Co-Ordinator.

### **7.4 Disposal**

The removal and safe disposal of any device needs to be considered under the Special Waste Regulations (NI) 1998. As identified special waste can include:

- Wastes containing metal
- Oil Wastes
- Waste from coolants
- Batteries
- Radioactive waste
- Waste from human or animal healthcare and/or research
- Waste from natal care, diagnosis or prevention of disease in humans

Consideration also needs to be given to the European Directive on Waste from Electrical and Electronic Equipment (WEEE) and the transport of Medical Devices prior to disposal i.e. returning to manufacturer. The Trust's process for managing the removal of obsolete equipment must be adhered to.

### **7.5 Transfer of Old or Obsolete Equipment**

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

- The Trust's disclaimer letter is completed.
- Transfer information is provided to the prospective purchaser whether for selling or donation. Where appropriate and depending on the risk of the device this should include: Documentation of decontamination, User manuals and training requirements, Service history and manual, Quality assurance test details.

## **APPENDICES**

## Appendix A

### 8.1 Medical Devices in Practice

The following lists illustrate examples of medical devices regularly used in the delivery of health and social care. These lists are not intended to be exhaustive.

Equipment used in the diagnosis or treatment of disease, or monitoring of patients, such as:

- Chiropody and podiatry equipment
- Dental instruments, equipment and materials
- Dressings
- Endoscopes
- Examination gloves
- Gastrostomy tubes
- Intravenous (IV) administration sets and pumps
- Nebulisers
- Ophthalmic equipment
- Peak flow meters
- Surgical instruments
- Suction equipment
- Syringes and needles
- Sphygmomanometers
- Thermometers
- Ultrasound dopplers
- Urinary catheters

Equipment used in life support, such as:

- Defibrillators
- Domiciliary oxygen therapy systems
- Insulin injectors
- Pulse oximeters
- Ventilators used in the home

In vitro diagnostic medical devices and their accessories, such as:

- Blood glucose measuring devices
- Cholesterol test kits
- Pregnancy test kits
- Specimen collection tubes
- Urine test strips

Equipment used in care, such as:

- Adjustable beds
- Lifting poles
- Patient hoists
- Pressure relief equipment
- Stoma care equipment

Equipment used by people with disabilities, such as:

- Bathing equipment
- Commodes
- External prostheses and orthoses
- Hearing aids
- Incontinence aids
- Prescribable footwear
- Standing frames
- Urine drainage systems
- Walking aids
- Wheelchairs and special support seating

Other examples include:

- Condoms
- Contact lenses and care products
- Intra-uterine devices (IUDs)

## Appendix B: Key Roles and Responsibilities

### 9.1 The following are the key personnel who have specific responsibilities within this policy:

1. Chief Executive
2. Director of Corporate Planning & Performance Management
3. Directors with nominated responsibility for Controls Assurance Standards
4. Medical Devices & Decontamination Working-Group
5. Assistant Directors
6. Professional Staff
7. Departmental Equipment Controller
8. Medical Engineering Manager/Technical Co-ordinator (Estate Services)
9. End User
10. Regional Supplies Services
11. Community Equipment Stores

#### 9.1.1 Chief Executive

The Chief Executive is ultimately accountable for the compliance, implementation and effective management of medical equipment and devices in accordance with statutory and National Health Service guidance standards.

#### 9.1.2 Director of Planning & Performance Management

The Chief Executive delegates to the Director of Planning & Performance Management responsibility for the management of technical servicing of all medical equipment and devices.

Estate Services Department has the responsibility for the management of technical servicing and has designated authority to deal with all technical aspects of the management of equipment, servicing and maintenance (See Technical Co-ordinator responsibilities below).

#### 9.1.3 Directors with nominated responsibility for Controls Assurance Standards

The Chief Executive has delegated responsibility for the Control Assurance Standards on the management of Medical Devices to the Director of Primary Care and Older People's Services/Executive Director of Nursing. This responsibility has been further delegated to the Asst Director of Workforce Planning and Modernisation who co chairs the Trust Medical Devices and Decontamination Working Group.

#### 9.1.4 Medical Devices & Decontamination Working-Group

The Medical Devices & Decontamination Working-Group exists within the Integrated Governance Structure and operates as a working group to Risk Management Sub Committee this working group is responsible for ensuring that appropriate policy and procedures are in place to ensure the effect management of decontamination of medical devices in accordance with controls assurance standards. The accountability arrangements are illustrated in appendix B

The Medical Devices & Decontamination Working-Group will also ensure an effective approach to the procurement of medical devices in respect of emerging new technology. The group will oversee a wide range of purchasing issues to improve the co-ordination between procurement, business planning, maintenance, risk management and training. These include, where appropriate:

- Technical specifications
- Financial data
- Regulatory compliance information
- Device/equipment evaluation reports
- User experience and preferences
- Comparing costs and features of alternative devices
- Standardising on a single model where possible or rationalise to the lowest possible number
- Maintenance and training implications
- Advise and support users, make recommendations where appropriate
- Provide feedback to groups as necessary

#### 9.1.5 Assistant Directors

The Assistant Directors have responsibility for the implementation, compliance and effective management of the medical equipment and devices within their Directorate.

#### 9.1.6 Professional Staff

All professional staff are responsible for the correct use and care of all equipment used by them. The staff must satisfy themselves that they are trained in the safe use of equipment. Staff must also ensure that the equipment is working correctly and follow decontamination procedures and if appropriate report any defects or faults immediately.

#### 9.1.7 Departmental Equipment Controllers

Each Department or Team should have a Departmental Equipment Controller (DEC) where medical equipment is used. In certain cases there may need to be more than one Equipment Controller.

The Departmental Equipment Controller is responsible to the nominated Head of Department for the following:-

- Be competent in the use of all medical devices regularly used within the Department and ensure that all other staff have been trained also by either the departmental equipment controller or (b) the company representative.
- Maintain an up-to-date asset register for the department in conjunction with Estate Services and in accordance with the Trust policy.
- Monitor equipment records/databases to ensure that repairs and servicing are carried out regularly and promptly.
-

- Liaison with the Medical Engineering Manager/Technical Co-Ordinator and Supplies Department from an early stage in the process of selection of new or replacement medical devices.
- Collaboration with the Technical Co-ordinator and Supplies Department in the preparation and revision of a planned replacement programme.
- Participate in acceptance of equipment into service and attendance/involvement at commissioning stage.
- Liaise with the Medical Engineering Manager/Technical Co-Ordinator in all aspects of the maintenance and servicing of medical devices.
- Ensure unused equipment is returned to the Equipment Library (Altnagelvin Hospital only) by contacting the Librarian or appropriate Community Appliance Stores.
- Ensure that all equipment for repair or planned maintenance is prepared in accordance with the Trust's Disinfection and Decontamination Guidelines (in section 9 of the Infection Control Manual)
- Report the receipt of soiled equipment from the Library or other departments as an Adverse Incident.
- Make provision for alternative patient care/treatment in the event of equipment failure.

#### 9.1.8 Medical Engineering Manager/Technical Co-Ordinator Responsibilities (Estate Services Department)

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

Responsibility of the Technical Co-ordinator includes:

- Providing technical advice on new devices and checking PPQ forms.
- Ensuring the 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 Estates, Supplies, Administration and the Equipment Controllers.
- Maintaining Inventories.
- Monitoring the safety of medical devices on loan, trial or rent.

#### 9.1.9 End User

The end user is the patient/carers.

#### 9.1.10 Regional Supplies Service

The Regional Supplies Service is responsible for ensuring compliance with all directives issued in respect of procurement of medical devices, including, securing best value for money, coordinating tender renewal processes and ensuring that the public sector is beyond reproach and incorporate legal protection for the Trust and its officers. RSS is also responsible for maintaining an inventory of all equipment in the Community. The Trust will work in partnership with RSS in respect of adhering to procurement procedures. RSS will

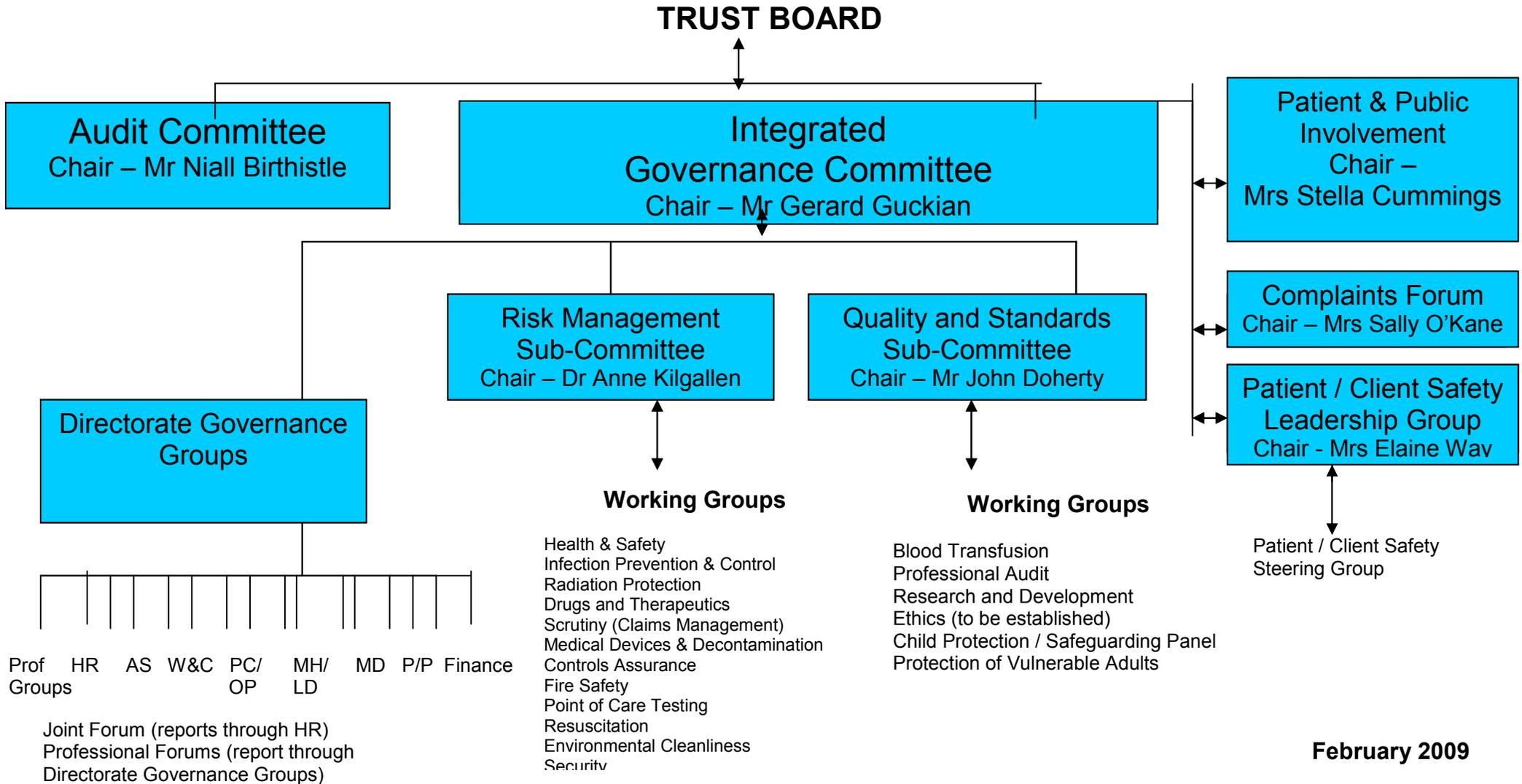
be represented on the Management and Decontamination of Medical Devices Working Group.

#### 9.1.11 Community Appliance Stores

Community Appliance Store maintains up-to-date inventory of all medical devices in the Community. The Community Equipment Controllers will work closely with Community Appliance Store staff.

Appendix C:

9.0 Accountability Arrangements for Integrated Governance - Western Health & Social Care Trust



February 2009

## **Appendix D**

### **10.1 Business Case Approval Process**

#### Table of Contents

Section 1- Context

Section 2- Approval Processes

## **Section 1 Context**

### **1.0 General**

The Standing Financial Instructions provide clear guidance on the requirements and responsibilities within the Trust of developing business cases.

These include:

- 1) That a business case, in line with the guidance contained within the “Capital Investment Manual”, is produced setting out an option appraisal of potential benefits compared with known costs to determine the option with the highest ratio of benefits to costs.
- 2) That the Director of Finance has certified professionally to the costs and revenue consequences detailed in the business case.
- 3) That DHSSPS approval is obtained for projects costing more than the Trust’s delegated limit for capital schemes.

In addition, Trust staff should only spend time on value added activities. In the context of business case preparation, the Trust should not commit significant time and resources to developing business cases for service developments that are not aligned to strategic or operational priorities.

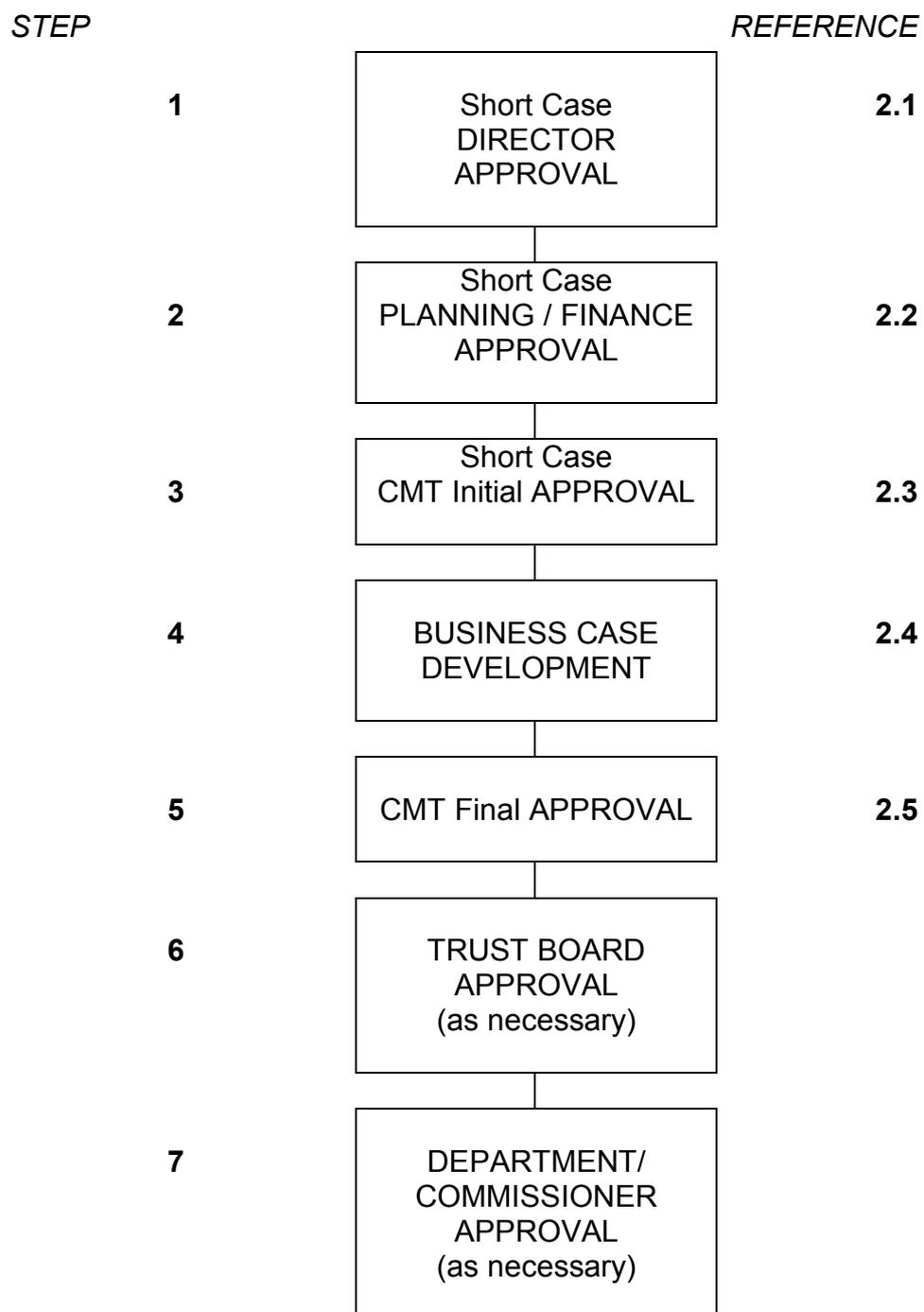
### **1.1 Capital expenditure- Approval Processes**

£0 - £150K	requires Corporate Management Team (CMT) approval
£150K - £500K	requires CMT and Trust Board approval
£500K	requires CMT, Trust Board and DHSSPS and Commissioner approval

### **1.2 Revenue expenditure- Approval processes**

**All** business cases with a revenue funding implication requires CMT/Commissioner approval.

### 1.3 Overview of Business Case Approval Process



## **Section 2 Business Case Approval processes**

Business cases should be commensurate with the value of the case and the following processes must be completed.

### **2.1 Director sign-off approval – Short Case**

In order to ensure that all developments are in line with the strategic direction of the Trust, and the operational direction of the Directorate, an approval proforma must be completed. This proforma must be developed by the lead Assistant Director & signed off by the relevant Director & clinical lead. This will ensure high level consideration of the proposal prior to any in-depth work being completed. The proforma should then be forwarded to the Assistant Director of Corporate Planning and the Assistant Director of Finance (Capital, Costing & Efficiency).

### **2.2 Planning / Finance Approval- Proforma/Short Case**

At this stage, both Assistant Directors of Planning and Finance will initially review the proforma, in conjunction with the lead Directorate-Assistant Director. This will involve a funding affordability assessment, feasibility review and strategic alignment evaluation.

If reviews are positive, the Approval to Proceed proforma will be presented to CMT for initial approval to proceed to business case development.

### **2.3 Initial CMT Approval – Proforma/ Short Case**

On presenting the Approval to Proceed proforma to CMT, any associated high level revenue and capital consequences must be identified together with an indication of the likelihood of Trust, Commissioner or DHSSPS financial cover, as appropriate.

If initial CMT support is secured then work can start on developing a commensurate business case.

### **2.4 Business Case Development & Planning Division Support .**

At this stage, a team will be put together with appropriate representation from Planning, Estates, Finance and Human Resources, which will be lead by the lead Directorate Assistant Director. Within each Directorate there is a planning and performance capacity which will be the “engine room“ to produce the individual elements that will make up the overall case. The Planning Division role will be to develop the project timetable, deliverables and ensure that all elements are produced to Green Book standard. This will be taken forward with the relevant representatives from the Trust’s Human Resources and Finance services to ensure full consideration of the development of firm funding arrangements.

As a working assumption, the following outline is intended to provide guidance of what commensurate business case means in practice:-

Capital/ Revenue cost  
£0K - £150K - will require approx 3-5 pages.

£150k + - will be subject to the specific requirements for business cases as set out in the Green Book standard.

**2.5 Submission of final business case to CMT, Trust Board, Commissioner, DHSSPS**

The finished business case will be submitted for approval to CMT, Trust Board, Commissioner & DHSSPS. (see 1.2 & 1.3 above)

## Appendix E

### 11.1 Medical Devices Acceptance Form

*Complete sections 1, 2, 5 & 6 and only section 3 or 4 as appropriate*

#### 1. LOCATION DETAILS

Directorate: \_\_\_\_\_ Location: \_\_\_\_\_

Equipment Controller: \_\_\_\_\_ Date Device is first placed in Service: \_\_\_\_\_

#### 2. DEVICE DETAILS

Asset ID: \_\_\_\_\_ Module of (Asset ID): \_\_\_\_\_

Supplier: \_\_\_\_\_ Manufacturer: \_\_\_\_\_

Device Type: \_\_\_\_\_

Model: \_\_\_\_\_ Serial No.: \_\_\_\_\_

#### 3. PURCHASE DETAILS

PurchaseDate: \_\_\_\_\_ PurchaseOrderNo.: \_\_\_\_\_ PurchaseCost: \_\_\_\_\_

Trust: Purchase  Gift

Commercial: Contracted  Lease  PFI  Warranty Period: \_\_\_\_\_

Service Agent: \_\_\_\_\_ Service Cover: \_\_\_\_\_

#### 4. LOAN DETAILS

Start Date: \_\_\_\_\_ Loan Period: \_\_\_\_\_ (Maximum 6 Months)

To be renewed:  *(Tick if required for another period)*

#### 5. ACCEPTANCE TEST

*Required N/A (Tick as appropriate)*

PPQ Acceptance OK

Functional Check OK

Performance Check OK

Electrical Safety Test Check OK

Acceptance Test Organisation: \_\_\_\_\_

Authorised Acceptance Tester

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

#### 6. Equipment Controller

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**11.2 NIAIC Adverse Incident Report Form**

**NIAIC ADVERSE INCIDENT REPORT FORM**

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

<b>Details of device:</b>			
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? <input type="checkbox"/>		If YES, was the manufacturer or supplier contacted? <input type="checkbox"/>	

<b>Incident Details :</b>		
Date of Incident	Was there a fatality? <input type="checkbox"/>	Was an injury caused? <input type="checkbox"/>
<b>Injury details:</b>		
<b>Nature of defect / details of incident:</b>		
<b>Action taken by staff :</b>		
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: Northern Ireland Adverse Incident Centre, Health Estates, Stoney Road, Dundonald, BT16 1US, Fax 028 90523900,  
Preferred method e-mail : [niaic@dhsspsni.gov.uk](mailto:niaic@dhsspsni.gov.uk)

Version 2008/1

## Appendix F:

### 12.1 Device on Loan Form

#### EQUIPMENT ON LOAN

#### STANDARD FORM OF INDEMNITY

#### HEALTH AUTHORITY

AN AGREEMENT made the day of ..... 20  
.....

BETWEEN: .....  
("The Trust")

and .....("The  
Supplier")

#### WHEREAS

- (1) The Supplier is the owner of the equipment described in the Schedule ("the equipment"/"device").
- (2) The Supplier wishes the Trust to use the equipment/device for the benefit of the Supplier for the purpose of evaluation, testing, research, design, investigation or trial demonstration.

**IT IS HEREBY AGREED** that the Supplier shall lend and the Trust shall borrow and use free of charge the equipment for the period specified in the Schedule in the premises specified in the Schedule ("the premises") on the terms set out below.

1. The loan of equipment/device shall be deemed to be a contract for the hire of goods as defined by Section 6 of the Supply of Goods and Services Act 1982. The contract shall be deemed to have been concluded in Northern Ireland and shall at all times be construed in accordance with the law in force in Northern Ireland.
2. The Supplier shall be liable for and shall indemnify the Trust and the Department of Health and Social Services against all liability in respect of personal injury to or the death of any person, loss or damage to property and any loss or expense in consequence of or in any way arising out of the installation, presence, use or removal of the equipment/device on or from the premises provided that this indemnity shall not extend to liability resulting from the negligence of the Trust's own servants or agents.
3.
  - a) The Supplier shall insure against its full liability under Condition 2.
  - b) The insurance cover shall be in the minimum sum of £5 million pounds for Product Liability and £10 million pounds for Public Liability in respect of any one incident.
  - c) The Supplier upon request shall produce to the Trust documentary evidence that the insurance is properly maintained.

- d) Should the Supplier default in insuring the Trust may itself effect insurance and may charge the cost together with an administrative charge of 5% to the Supplier.
- 4. The Supplier shall provide the Trust with written evidence on the safety of the equipment/device, drawing attention to any failures to comply with relevant British Standards/DHSSPS specifications or other standards and specifications and Health Estates guidance paper DB9904(NI) July 1999 (& Supplement 1/ May 01) concerning the management of Medical Devices & equipment in hospital & community based organisations or any aspect of safety that has not been fully tested. Restrictions on the use of the equipment/device necessary to ensure the safety of patients or staff shall be pointed out to the Trust.
- 5. The Supplier shall ensure that the equipment complies with the Medical Devices Directive 93/42/EEC – CE Marking.
- 6. Detailed instructions in the use of the equipment shall be given to the Authority’s nominated staff by a qualified agent of the Supplier and detailed instructional manuals, where available, shall be supplied to the Authority.
- 7. The equipment will not be modified or interfered with by the Authority without the agreement of the Supplier.
- 8. The Authority shall not be liable for any charge for maintenance, repair, consumable materials and accessories required for the operation of the equipment during the period of the loan or for any carriage or installation charges except by prior notification to and the issue of an official purchase order by the Authority.
- 9.
  - a) On receipt of a written request at any time from the Authority the Supplier shall remove the equipment from the premises with all practicable speed free of charge and at the time provide the Authority with a receipt for the equipment.
  - b) The Authority shall permit the supplier to remove the equipment from the premises on receipt of reasonable notice in writing.
  - c) The Supplier will be responsible for the costing of reinstating the premises, including the services therein, to the satisfaction of the Authority.
- 10. The equipment shall remain continuously at the Supplier’s risk during and after the period of the loan.

SIGNED on behalf of the Authority:.....

SIGNED on behalf of the Supplier:.....

## THE SCHEDULE

1. The Equipment

Model/Mark No:

Value:

Description:

2. Period of Loan

..... years ..... months commencing the ..... day of .....  
20.....

3. The Premises

HEI No. 98 January 1991

**Appendix G**

**13.1 Medical Device on Loan to Patients**

**MEDICAL DEVICE LOAN FORM**

<p><b>PATIENTS DETAILS:</b></p> <p><b>Name:</b></p> <p><b>Address:</b></p> <p><b>Hospital Number:</b></p>	<p><b>COMMUNITY TEAM DETAILS:</b></p> <p><b>Name District Nurse:</b></p> <p><b>Health Centre:</b></p> <p><b>Telephone Number:</b></p> <p><b>OR</b></p> <p><b>Transfer Details:</b></p> <p><b>Name Hospital/Hospice:</b></p> <p><b>Ward:</b></p> <p><b>Contact Telephone Number:</b></p>
<p><b>LOCATION DETAILS:</b></p> <p><b>Loaned from Ward</b> <b>To</b> <b>Date</b></p>	<p><b>DEVICE DETAILS:</b></p> <p><b>Device Type</b> <b>Model</b> <b>Asset ID Number</b></p>
<p><b>SPECIAL INSTRUCTIONS:</b> Syringe Drivers should be returned within 48hours in the Addressed Jiffy Bag provided with this form</p>	

**Signature of lender:** \_\_\_\_\_

**Please return to Ward/Dept:** \_\_\_\_\_

**Date returned to Ward/Dept:** \_\_\_\_\_

**Signature of recipient:** \_\_\_\_\_

**Returned to Equipment Library on:** \_\_\_\_\_

**Appendix H**

**14.1 Decontamination Certificate**

**WESTERN HEALTH & SOCIAL CARE TRUST**

**DECLARATION OF DECONTAMINATION**

The appropriate boxes and verifying signature should be completed by Ward/Unit Staff.

Title of Equipment/Item(s):- \_\_\_\_\_

Asset ID No.:- \_\_\_\_\_ Ward/Unit:- \_\_\_\_\_

- A  This equipment/item has not been used in any invasive procedure or been in contact with blood, other bodily fluids, respired gases or pathological samples.
- B  This equipment/item has been exposed internally or externally to hazardous materials as indicated below.

Blood, body fluids, respired gases, pathological samples: **YES/NO**

Chemicals or substances hazardous to health: **YES/NO**

**This equipment/item could not be dismantled before cleaning/disinfection:**

**This equipment/item has been cleaned using hot water and detergent:**

**This equipment/item has been disinfected using:**

	<b>Strength</b>	
	<b>1,000ppm</b>	<b>10,000ppm</b>
Chlorine releasing agent Milton or Equivalent	<input type="checkbox"/>	<input type="checkbox"/>
Alcohol 70%	<input type="checkbox"/>	
Other	_____	

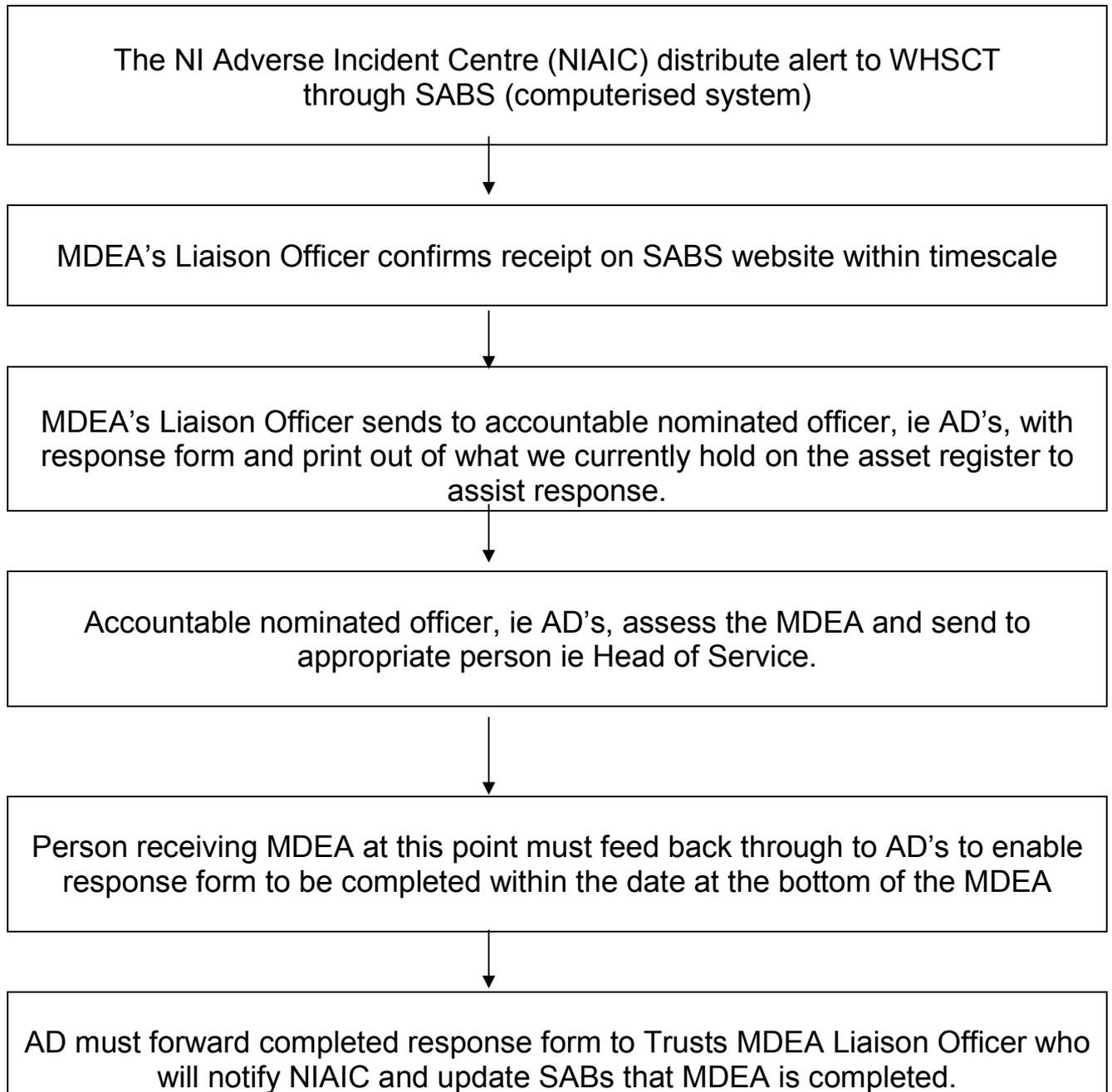
**Signature of Member of Staff:** \_\_\_\_\_

**Printed Name:** \_\_\_\_\_

**Position:** \_\_\_\_\_ **Date:** \_\_\_\_\_

Appendix I

MEDICAL DEVICE EQUIPMENT ALERT



## 15 Equality and Human Rights

EQUALITY AND HUMAN RIGHTS STATEMENT: The Western Health and Social Care Trust's equality and human rights statutory obligations have been considered during the development of this policy.

Signed: \_\_\_\_\_(Chairman)

Date: \_\_\_\_\_