Western Health and Social Care Trust

Policy for the Management of Medical Devices

Date:- September 2021

Review Date:- September 2023

Western Health and Social Care Trust

Title	**Policy for the Management of Medical Devices**
Reference Number	Corp09/14
Implementation Date	July 2011
Review Dates	November 2014 November 2016 September 2021
Next Review Date	**September 2023**
Responsible Director	Dr Bob Brown Director of Primary Care and Older Peoples Service/Executive Director of Nursing
Lead Officer	Brendan McGrath, Assistant Director of Nursing

Western Health and Social Care Trust

Contents

1 INTRODUCTION
- 1.1 Management Structure
- 1.2 Medical Devices 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 Medical Device Acceptance Form 9A
- 3.4 Equipment Registration
- 3.5 Storage of New Devices
- 3.6 Prescription of Medical Devices
- 3.7 Medical Devices on Trial, Loan or Rent
- 3.8 Medical Devices on Loan to Patients/Carers
- 3.9 Medical Device Modification
- 3.10 Medical Device Vigilance
- 3.11 Medical Device Adverse Incident Reporting
- 3.12 MDEA Alert Management
- 3.13 Networked Medical Devices

4 TRAINING
- 4.1 Professional 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
7.6 Charitable Donation of Medical Device

8 APPENDIX A
8.1 Medical Devices in Practice

9 APPENDIX B
Accountability Arrangements for Integrated Governance

10 APPENDIX C
10.1 Roles & Responsibilities
10.1.1 Chief Executive
10.2.2 Director of Corporate Planning & Performance Management
10.2.3 Directors with Nominated Responsibility for Corporate Standards
10.2.4 Medical Devices Working-Group
10.2.5 Assistant Directors
10.2.6 Professional Staff
10.2.7 Departmental Equipment Controllers
10.2.8 Senior Medical Engineering Manager
10.2.9 End User
10.2.10 Procurement and Logistics Services (PaLS)
10.2.11 Community Appliance Stores

11 APPENDIX D
11.1 Pre-Approval Questionnaire Form

12 APPENDIX E
12.1 Business Case Approval Process

13 APPENDIX F
13.1 Medical Equipment Asset Registration Form

14 APPENDIX G
14.1 Medical Devices Acceptance & Registration Form

15 APPENDIX H
15.1 Acceptance & Maintenance Procedures

16 APPENDIX I
16.1 NIAIC Adverse Incident Report Form

17 APPENDIX J
17.1 Medical Device on Loan Form

18 APPENDIX K
18.1 Medical Device on Loan Form to Patients

19 APPENDIX L
19.1 Declaration of Decontamination Certificate

20 APPENDIX M
20.1 Medical Device Equipment Alert Management Process

21 APPENDIX N
21.1 Equipment Condemnation Notice

22 APPENDIX O
22.1 Disposal of Equipment Form

23 APPENDIX P
23.1 Donation Agreement Form

24 APPENDIX Q
24.1 Assets Donation Form

25 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 "Managing Medical Devices Guidance for Health Care & Social Services Organisations" Medicines & Healthcare products Regulatory Agency (MHRA) Jan 2021, and all subsequent guidelines. The policy has been developed 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 guide staff on 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, consumables, maintenance, training and the maintenance of training records, infection prevention and control / 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, consumables used in these processes.
    - 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 B** which illustrates the Medical Devices Working Group within the Trust's Governance Committee show how this will be achieved for medical device management within the Trust. See Appendix B for organisational arrangements.

1.2 Medical Devices Working Group

The Medical Devices Working Group will ensure that effective systems are in place to manage the Trust stock of medical devices. 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
- Infection Prevention & Control / 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 and decontamination 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 Working Group to ensure that these needs are met.

The Head of Department retains ultimate responsibility for the management of the medical devices used in the delivery of care and treatment within their Ward/Dept, this responsibility maybe delegated to a Departmental Equipment Controller (DEC), who has day to day responsibility for the equipment, maintaining an inventory of the equipment and liaising with the Senior 'Medical Engineering Manager' on all matters relating to the technical management and maintenance 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 C.**

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. 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 with revenue 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. As a result of Cyber-attacks and other Cyber related events in healthcare, any new or replacement equipment that is, or is intended to be, connected to the Trust ICT network must be assessed by the ICT security team prior to purchase and connection to the Trust network. A WHSCT ICT 3rd party Security and Technical questionnaire is available to be completed by departments and the suppliers. Requestors and suppliers need to be aware that where the equipment is a PC, Laptop or Tablet that is connected to the Trust network, it's operating system should be "in support", e.g. Windows 10 (at time of this publication), and have the most up to date security patches applied. 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. If device selection includes non-standard devices then a user evaluation programme should be considered. The Trust's Purchasing Procurement Procedure is presented as a flowchart overleaf.

A Procurement sub group of the Medical Devices Working Group reviews and scrutinise requests to purchase Medical Devices/Equipment.

To provide the Medical Devices Procurement Group with necessary information to support procurement decisions a Pre-Approval Questionnaire must be completed to accompany the Requisition. A copy of the Pre-Approval Questionnaire is attached at **Appendix D**

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 the need to select appropriate devices adherence to the Trust's Procurement Procedure. Donated devices without CE marking must not be accepted into service.

2.1 Business Case Proforma Completion

The Western Trust has in place a process to ensure that any request to support the purchase of 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 template must be completed for each new request devices individual greater than £1,000 see below and submitted to the Assistant Director of Finance Capital Planning. A copy of the Business Case Template is attached at **Appendix E** for information. This will provide high level information to allow further decision to be made. The template 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 Business Case Review Group and submitted to Corporate Management Team. 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 Capital Planning and seek assistance in expediting the process.

Devices valued greater than £1000

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 template 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.

Assessment must also be made of

- Maintenance implications, including staff and equipment costs
- Estimated annual usage of consumables
- Compatibility with existing equipment
- Specific requirements for installation
- Training requirements and frequency of update training.
- Cleaning/Decontamination

2.2 Ordering

When placing orders for medical devices the Requester/HOD/Departmental Equipment Controller must liaise with the Trust Senior Medical Engineering Manager, Estates Services Department and HSDU regarding:

- Installation of the device – Acceptance Testing & Asset Registration
- 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 and frequency of update training if required.
- Appropriate testing and validation certificates to be supplied with the device.

3.0 ACCEPTANCE AND INTRODUCTION OF MEDICAL EQUIPMENT

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

<u>Community</u>

If the equipment is for use by District Nursing specifically, the acceptance tests must be carried out by the Team Leaders. For community medical devices, 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 will be directed to the requisitioner. The person receiving the device is responsible for initiating the acceptance process by completing the Acceptance and Introduction of Medical Equipment Form (sample form and guide to completion attached **Appendix F**):

The Head of Department or nominated Department Equipment Controller will have ultimate responsibility for ensuring completion of the Trust Acceptance and Introduction of Medical Equipment Form.

3.2 Acceptance Testing

Completion of the Trust Acceptance and Introduction of Medical Equipment Form will ensure compliance in the following areas:

- Checking of the delivery documentation to ensure that the correct product has been received 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/PALS that the device is formally accepted so that payment can be made.
- Ensuring that the device, if required, is tested for electrical safety prior to installation by the Medical Equipment Technician/Engineer.
- 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.
- Copy of manufacturers' instructions/Guidance to be available within the department and forwarded to the Chair of the Medical Devices Working Group and to be uploaded on the Intranet Library.

3.3 Medical Device Acceptance & Asset Registration Form 9A

Medical Device Acceptance & Asset Registration Form **(Appendix G)**
The Medical Equipment Asses Registration Form 9A is shown in Appendix F and the medical equipment registration process as outlined in the flowchart on the reverse of the form is also shown. The 9A Form is completed by Estates staff as per the registration process.

3.4 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 Equipment Asset Registration Form 9A will

be transferred on to the Trust's computerised equipment management system Backtraq. 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.

A copy of the document completed by the Estates Services Medical Engineer Team is attached at **Appendix H**.

3.5 Storage of New Devices

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

In particular Ward Sisters/Charge Nurse/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
- Charging devices are industrial standard and approved by the estates department
- 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 (SWAH, Tyrone & Fermanagh Hospital & Gransha Hospital) Sub stores in Community for emergency items
- All Health Centres have sub-stores for a small number of medical devices

3.6 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 is responsible for ensuring that procedures are in place to ensure that suitably qualified and experienced staff undertake the prescription of medical devices.

3.7 Medical Devices on Trial, Loan or Rent

A 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 I)**

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. It is recommended that the loan period is identified and limited to a period of time if required.
Any medical device, which requires decontamination via HSDU, must arrive in HSDU at least 48 hours before intended use.

The Ward Sisters/Charge Nurses/Heads of Department/Locality Managers must

- Ensure that Devices on Loan Form is satisfactorily completed, received prior to delivery of the medical device and kept on file. On occasions the supplier may ask to have their own loan agreement signed. In these cases both documents must be completed.
- Instruct the supplier to contact the Head of Dept/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.
- Notify the Senior Medical Engineering Manager who 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 a Device on Loan Form has been received prior to delivery of the device.
- 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 suppliers to staff, provided:

- The suppliers 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.

3.8 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 including out of hours support.
- A record of the medical device on loan should be maintained to ensure return of equipment.
- Medical devices are collected after use by the Directorate representatives or orgainsed through the commercial owner if required.

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

Communication with service users/families/carers

Western Trust staff are committed to improving people's health and social care and to make sure that people can understand the information they are given about their health and care. Some people will need information in a different format, or help to communicate or explain what they think. They may need written information in large print, braille, easy read, in another language or by email. Service users or their family or carers may need a sign language interpreter or foreign language interpreter. In line with Trust guidelines and policies staff should ensure that communication support needs are met when in receipt of Medical Devices.

3.9 Medical Device Modification

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

3.10 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 Directors 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 Medical Device Adverse Incident Reporting

Adverse incidents involving a medical device, non-medical equipment or plant should be reported on Datix and a report forwarded to NIAIC, especially if the incident has been associated with or could lead to:

- Death, life-threatening illness for injury
- Deterioration in health or permanent impairment of body structure or function
- The necessity for medical or surgical intervention (including implant revision)
- Hospitalisation or prolongation of existing hospitalization
- Unreliable test results and associated risk of mis-diagnosis or inappropriate treatment
- death, congenital abnormality or birth defect
- Ongoing faults that successive service/maintenance visits have failed to rectify
- Fetal distress

Following the death of a patient all medical devices associated with that patients care must be quarantined as part of the incident investigation process.
The NIAIC form is available at:
https://www.health-ni.gov.uk/publications/niaic-adverse-incident-reporting-guidance-and-forms

Sample Form at **Appendix K.**

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 MDEA 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 L**.

3.13 Networked Medical Devices

With developments in technology a number of the medical devices used in the delivery or health care now have the capacity to be networked to facilitate the transfer of clinical data from the patient to a central processing unit or retained within the memory of the actual device.

It is important that Departments that have networked medical devices or planning to procurement such devices ensure that system security updates and routine maintenance are procured when making the initial purchase. It is the responsibility of Suppliers to ensure that medical devices that contain computers have the most up to date level of system security and to have audio-visual (AV) protection included.
Within the Cyber community in the NHS, third party devices and how they are managed present a significant Cyber risk to healthcare.

NHS Digital may issue Care Certificates regarding the ICT aspects of medical alerts. Reports of cyber-attacks where the integrity of a network linking a medical device and its monitoring of a patient's condition has been breached. The Trust ICT Team need to be informed about any such alerts.

4.0 TRAINING

The Ward Sisters/Charge Nurses/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, this will include the maintenance of accurate records. 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/Initial calibration
- Proper use of device including any necessary cleaning/decontamination
- Identify and correct malfunctions

Where a new device is being introduced into a Department 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 Sisters/Charge Nurses/Team Leaders/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 Sisters/Charge Nurses/Team Leaders/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. Hospital Facilities – A shared drive resource has been established to provide templates for recording training information.

5.0 MEDICAL DEVICE/EQUIPMENT MAINTENANCE

Keeping medical devices safe and fit for purpose requires both routine maintenance procedures supervised by professional users, an appropriate maintenance regime including planned preventative maintenance or repair on demand maintenance carried out by suitably trained technicians or specialist contractors.

The Flowchart shows the WHSCT Medical Equipment Estates Acceptance & Maintenance Procedures: **Appendix L**

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. Readers are referred to the Trust's Infection, Prevention & Control Policy document for further guidance on the cleaning of medical equipment.

5.2 Planned and Breakdown (Repair on demand) 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 Senior Medical Engineering Manager together with Head of Department /Departmental Equipment Controller is responsible for co-ordinating and managing the maintenance and servicing of all medical devices. All electromedical devices are required to be periodically safety tested. A certificate of decontamination must be completed prior to any services or repair.

5.3 Guidelines on Decontamination

The decontamination of medical devices/equipment falls into two categories

Category 1 Surface cleaning with Detergent or other approved product

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 Prevention & Control Team

Category 2 Chemical or Heat decontamination 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 Policy.
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 Policy. This includes the requirement to complete a certificate of decontamination.

Devices used by high –risk patients:

It is the responsibility of the user (ward staff/community 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 M)**
- 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 Working Group will be responsible for identifying the need for replacement programmes for commonly used equipment. 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. A copy of the condemned notice must be processed with the Pre-Approval Questionnaire.

(Refer to Section 2 – Purchasing Procurement Procedure Flowchart)

Note – A device may be nearing the end of its functional life but still in perfect working order. In these instances it is recommended that Head of Department/Departmental

Equipment Controller plan to replace the medical device, especially where it is service dependent.

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 Department Equipment Controller for the respective department must notify the Estates Department to request an 'Estates Management – Equipment Condemnation Notice' **(Appendix N)** be completed. The Departmental Equipment Controller requesting the condemnation will be required to sign the 'Condemnation notice' and a competent person (Estates or Service Contractor) will countersign to condemn the device. A copy of the condemned notice should be retained by the Departmental Equipment Controller to permit disposal. A copy should also be given to the Estates Backtraq Asset Co-ordinator to enable the asset register to be updated with all relevant details. Note: all medical devices must be decontaminated before condemnation can take place.

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 Senior Medical Engineering Manager Estate Services.

7.4 Disposal

The removal and safe disposal of any used medical devices needs to be considered under the relevant Waste Regulations. As identified waste can include:

- Metal
- Oil Wastes
- 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 latest Waste Electrical and Electronic Equipment Regulations (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 as detailed in the Trust's Waste Manual must be adhered to.

To arrange for disposal of a 'condemned' medical device, the Department Equipment Controller must complete a 'Disposal Form' to which the 'condemned notice' must be attached. The completed Disposal Form and Condemination Notice Form should together be returned to Estates who will organise the collection and disposal of the device.

With regard to networked devices with an internal disk drive which recorded confidential data including patient details it is important that the ICT are contacted to remove the confidential data and issue a disposal certificate prior to the device being disposed of or donated.

Disposal Forms (see sample form **Appendix O**) are available via the Trust Intranet under Useful Documents, Section E, Estates Disposal of Equipment Request.
Completed Disposal Form AND Condemnation Notice to be returned to: waste.management@westerntrust.hscni.net or return by post to: Waste Management, Estates Services Department, Altnagelvin Hospital, Londonderry.

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 maintenance manual, Quality assurance test details.
- The obsolete equipment is removed from the database.
- Approval to donate the equipment to a Registered Charity may be granted through the Directorate Governance Committee.

7.6 Charitable Donation of Medical Devices

The donation of a medical device is a process whereby the Trust transfers the ownership of a device to a third party to facilitate the continued use of the device after the life cycle of the medical device has expired or the device has been replaced with a new model. Occasions may arise were a member of staff is approached by a Charity looking to avail of such opportunities. The practice of donation is allowed within the Trust however there are rules that govern this process.
If a medical device has been identified by a member of staff for donation the
4 principles of donation MUST be followed.

1st Principle: The equipment must have a full service history.
It is essential that the equipment that is to be donated is in full working order and has been serviced in full throughout the course of the life cycle within the Trust. If this service history is not able to be confirmed then the medical device cannot be donated.

2nd Principle: The equipment must have a full user history.

The user history is important in offering an assurance that the medical device has been used correctly during the life cycle. This should be able to be confirmed by the staff member donating the device.

3rd Principle: The charity identified to receive the donation MUST be a registered charity with the Northern Ireland Charities Commission.

The Charity to receive the device(s) MUST have a live pin number with the Northern Ireland Charities Commission. This ensures that the charity is a legally registered organisation and offers the Trust a reassurance that the donated equipment will be received and donated in the correct manner.

If any of the first three principles are unable to be met then the donation of the equipment cannot go ahead and the equipment should be disposed of using the normal Trust process.

Only when all of the first three principles are met can the staff member move to completing the 4th principle.

4th Principle: If the equipment for donation still has a financial value it must only be donated after Director sign off:

- 1. Details of the equipment including the asset number have been sent to Financial Accountant for Capital, Systems and Governance to enable a value to be confirmed. This value will be detailed back to the requesting staff member.
- 2. If the asset for donation still has a financial value the Director of that specialty must consent to the donation. The Director must be informed of the outstanding value and make a decision as to whether or not the donation can proceed.

Assuming that all 4 principles are completed the staff member can move to the next part of the process and complete the following documents.

1. WHSCT Donation Agreement Form - Appendix P
2. WHSCT Assets Donation Form - Appendix Q

Both of these forms **MUST** be fully completed prior to the medical device donation

These forms will ensure that the Trust has documented evidence of the donation and also explains the commitment the receiving charity is undertaking and the liabilities there in.

The declarations within these documents MUST be completed / signed by both a WHSCT staff representative and a representative of the receiving charity.

A Trust condemnation form will be required for each medical device approved for donation however Estates need to be informed that the equipment will be for donation and not disposal.

When the process of donation is completed the asset(s) of the donated item(s) **MUST** be sent to Estates and Financial Accountant for Capital, Systems and Governance to ensure that the medical device(s) are removed from the Trust inventory / service contracts and financial databases.

All completed forms MUST be held securely within the Ward / Department that donated the equipment. A copy of the forms should be given to the charity.

APPENDICES

Appendix A: 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
- Prescribed footwear
- Standing frames
- Urine drainage systems
- Walking aids
- Wheelchairs and special support seating

Other examples include:

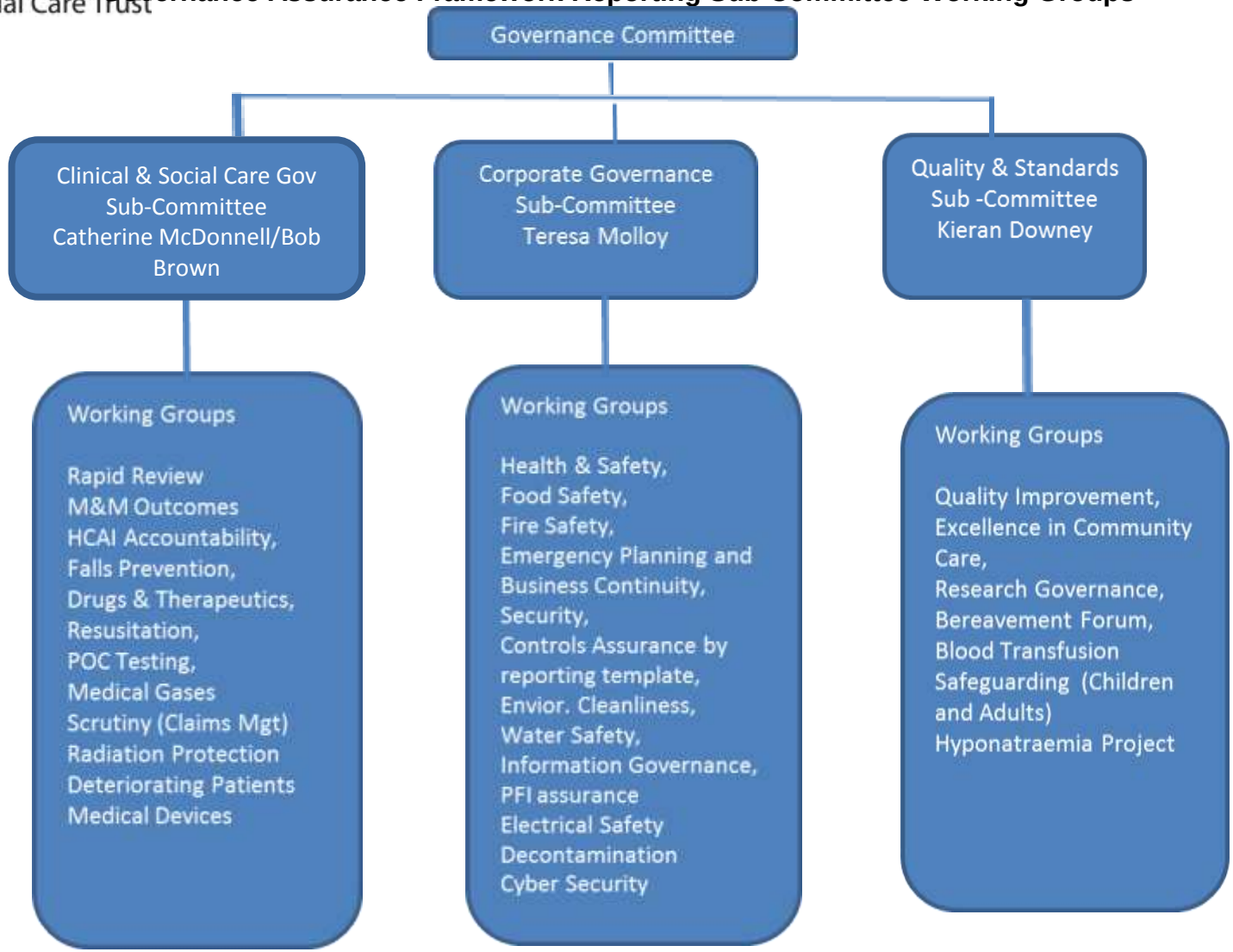
- Condoms
- Contact lenses and care products
- Intra-uterine devices (IUDs)

Consumables used in the delivery of care and treatment included Syringe, Needles, Fluid Blood Administration Sets, Tubing connecting the medical Device to the patient.

Western Health and Social Care Trust

Appendix B:

Governance Assurance Framework Reporting Sub Committee Working Groups



Appendix C: Key Roles and Responsibilities

C1 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 Corporate Standards
4. Medical Devices Working-Group
5. Assistant Directors
6. Professional Staff
7. Departmental Equipment Controller
8. Senior Medical Engineering Manager (Estate Services)
9. End User
10. Procurement & Logistics Services (PaLS)
11. Community Equipment Stores Team

C2 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.

C3 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).

C4 Directors with nominated responsibility for Corporate Standards

The Chief Executive has delegated responsibility for the Corporate 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 chairs the Trust Medical Devices Working Group.

C5 Medical Devices Working-Group

The Medical Devices 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 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

C6 Assistant Directors

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

C7 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.

C8 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 Senior Medical Engineering Manager and PaLS from an early stage in the process of selection of new or replacement medical devices.
- Collaboration with the Technical Co-ordinator and PaLS 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 Senior Medical Engineering Manager 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.

C9 Senior Medical Engineering Manager 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, PaLS, Administration and the Equipment Controllers.
- Maintaining Inventories.
- Monitoring the safety of medical devices on loan, trial or rent.

C10 Service User

The end user is the patient/carer

C11 Procurement and Logistics Service (PaLS)

Procurement and Logistics Service is responsible for ensuring compliance with all procurement directives and policies including any in respect of procurement of medical devices. PaLS is also responsible for maintaining an inventory of all equipment in the Community. The Trust will work in partnership with PaLS in respect of adhering to procurement procedures. PaLS will be represented on the Management and Decontamination of Medical Devices Working Group.

C12 Community Appliance Stores

Community Appliance Store maintains up-to-date inventory of stock medical devices used within the community compliance store. A comprehensive list of all equipment is recorded on MEASALS database. The Community Equipment Controllers will work closely with Community Appliance Store staff.

Western Health and Social Care Trust

Appendix D:

WESTERN HEALTH & SOCIAL CARE TRUST
PRE APPROVAL QUESTIONNAIRE

All non-catalogue requisitions for medical equipment must be approved by the Procurement Sub-Group. This form must be completed by an Authorised Signatory and attached to the requisition on E-Procurement.

This form does *not* have to be completed for the following:

Equipment already on the eProcurement catalogue

Furniture Fixtures or Fittings	Welch Allyen Diagnostic Sets	X-Ray or Lab equipment
Salter Aire Elite Nebuliser	Temporal Thermometer	Seca Scales to Class 3Laerdal
Suction Units	Nonin Pulse Oximeter	Littmann Classic Stethoscope

All individual items > £1000 must be accompanied by a Business Case Pro Forma.
All equipment > £10,000 must be tendered. PaLS will provide advice based on current legislation.

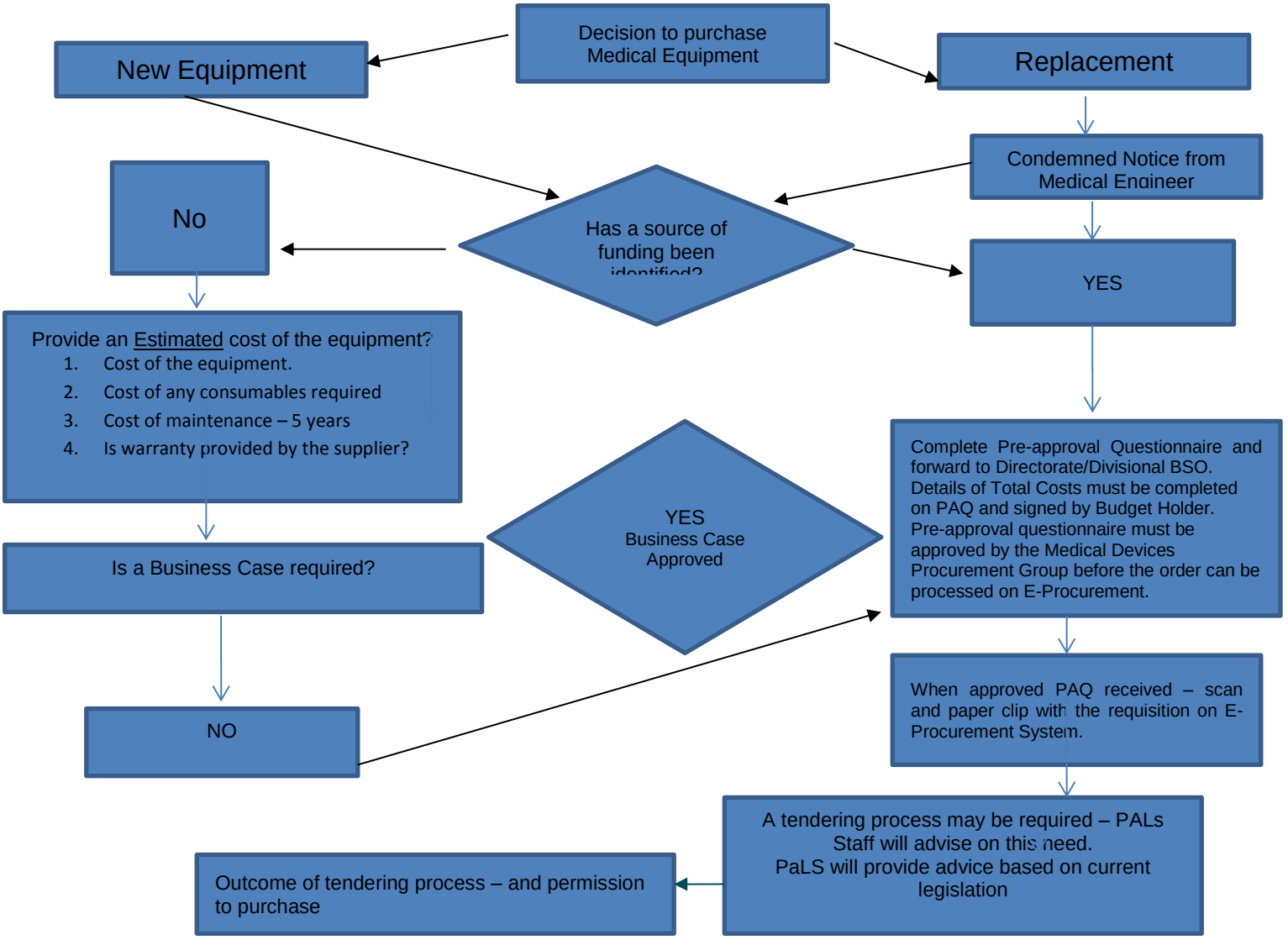
ITEM			
ESTIMATED ITEM COST		SERVICE/DEPARTMENT	
COMPLETED BY		DESIGNATION	
CONTACT TELEPHONE		DATE	

INFORMATION			RESPONSE & DETAILS
	Yes	**No**	
Is this equipment available on eProcurement catalogue? **If yes** please state reason for buying off catalogue			
What is the primary function of this equipment?			
Is this new or replacement equipment? **If replacement equipment – please ensure the condemned notice is attached.**			
What is the funding? Capital known as a C code Revenue known as a V Code E&G which requires an EG1 form			
Does this equipment need to be compatible with existing equipment within your department? If Yes please provide details and reasons for compatibility.			
Is this equipment in use elsewhere in the Trust? If so, where and are there any difficulties with it?			

Detail how this equipment is to be cleaned or decontaminated in accordance with Manufacturer's instruction or Trust Policy. You may need to speak to Infection Control staff Ext 213810 or HSDU staff Ext 213885 about this.	HSDU	
	Surface Applied Cleaning Product	
	Detergent	
	Specialist Cleaning (***Please give detail of product & method)***	
Revenue costs: <u>These must be identified</u> Are consumables or maintenance required for the operation of this equipment? If so please provide: You may need to speak to Estates Manager – Paddy McNulty – Ext 214590	Details of Consumables	
	Estimated Annual Usage / Cost	
	Annual Maintenance Costs	£

	TOTAL REVENUE COSTS	£
Approved by Head of Service / Budget Holder	SIGNATURE:	
PROCUREMENT SUB GROUP APPROVAL For Official Use Only		
ACTION: APPROVED / NOT APPROVED	**SIGNATURE:**	**DATE:**

Process for Procuring Medical Equipment



Western Health and Social Care Trust

Appendix E: 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.

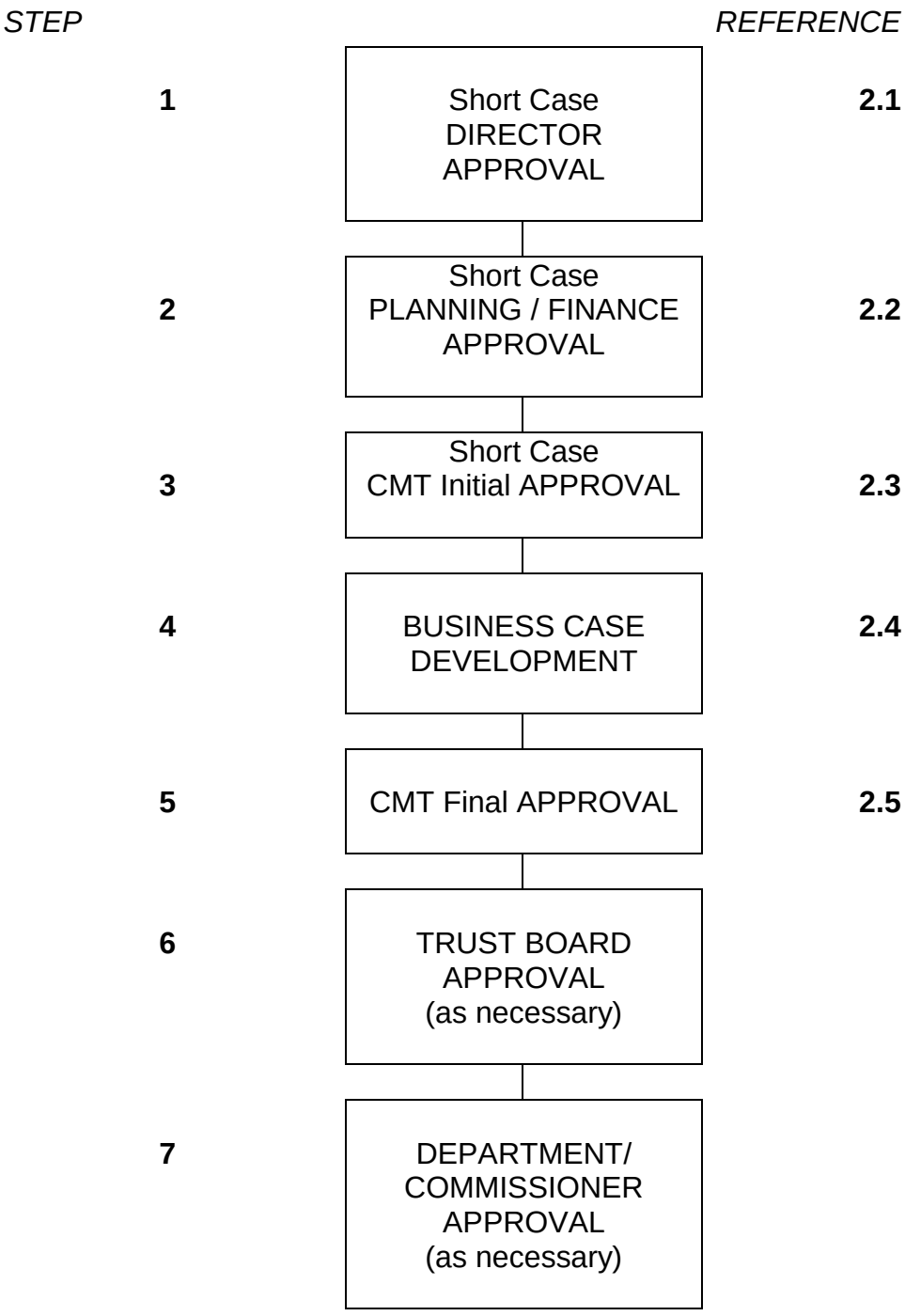
1.1 Capital expenditure- Approval Processes

£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 F

Western Health and Social Care Trust

FORM 9A
Version 7.2 at 13-12-11

MEDICAL EQUIPMENT ASSET REGISTRATION FORM

1 Location Details	
Directorate:	
Building & Dept/ Ward:	
Room & Room No. if applicable:	

2 Device Details			
Make/ Manufacturer:			
Model:		Serial Number:	
Description of Equipment:			

3 Purchase Details					
Delivery date of new item:		Order No:		Warranty Period:	
Cost centre:		Purchase Cost: £		Equipment put into service date:	
Equipment Supplier:					

4 Estates Staff Electrical Safety Test			
Electrical safety test completed: Yes, No or N/A (Not Applicable). If yes please attach test print out to this form.			
PRINT NAME		**Signature**	

5 Estates Staff Calibration Checks (where required and not available from DEC)			
Calibration Checks completed: Yes, No or N/A (Not Applicable). .			
PRINT NAME		**Signature**	

6 Proposed Service Requirements (if known)							
Contractor, Comprehensive		Contractor, PPM		In House Servicing		Contractor, Repairs Only	
Service due date:		Warranty period:		Contract to be renewed: (YES if required for another period)			
Service Provider:							

7 Equipment Controller Details			
Name:		Telephone number	
Signature:			

Asset ID		**Issue Date:**		**Date of Manufacture if known**	
Estates EMATS Administrator/ Librarian. Print name:		**Signature** **Date**			

INVENTORY REGISTRY FORM Version 7.2 at 13-12-11 for tvolno.doc

printed 12/14/2011

Western Health and Social Care Trust

Version 1.0 dated 07-12-2011

DRAFT WHSCT MEDICAL EQUIPMENT REGISTRATION PROCESS

Wednesday, 14 December 2011

ALTNAGELVIN HOSPITAL	SOUTHERN SECTOR COMMUNITY	NORTHERN SECTOR COMMUNITY
• Equipment arrives in department.	• Equipment arrives in department.	• Equipment arrives in department.
ACCEPTANCE • DEC prepares Acceptance Form	**ACCEPTANCE** • DEC prepares Acceptance Form	**ACCEPTANCE** • DEC prepares Acceptance Form
REGISTRATION • DEC contacts Altnagelvin Estates Helpdesk to request a job on EMATS by ringing ext. 212222 or 028 7186 5180	**REGISTRATION** • DEC contacts Omagh Estates Helpdesk to request a job on EMATS by ringing ext. 5111 or 028 8283 5111	**REGISTRATION** • DEC contacts Altnagelvin Estates Helpdesk to request a job on EMATS by ringing ext. 212222 or 028 7186 5180
ASSET LABEL • Equipment Librarian picks up job from EMATS & attaches Trust Asset Label to equipment.	**ASSET LABEL** • MTO picks up job from EMATS & attaches Trust Asset Label to equipment.	**ASSET LABEL** • MTO picks up job from EMATS & attaches Trust Asset Label to equipment.
TESTING • Equipment Librarian completes Asset Registration Form 9A, (electrically tests if necessary) & attaches electrical test certificate to Registration Form 9A.	**TESTING** • MTO completes Asset Registration Form 9A, (electrically tests and calibrates equipment if necessary) & attaches electrical test certificate plus manufactures calibration certificate to Registration Form 9A.	**TESTING** • MTO completes Asset Registration Form 9A, (electrically tests and calibrates equipment if necessary) & attaches electrical test certificate plus manufactures calibration certificate to Registration Form 9A.
CALIBRATION • For equipment requiring a calibration certificate Equipment Librarian a) Acquires manufacturers calibration certificate from DEC or b) If cert. not available then MTO to carry out Calibration Test & provide a calibration certificate.	**CALIBRATION** • For equipment requiring a calibration certificate MTO Acquires manufacturers calibration certificate from DEC or If cert. not available then carries out Calibration Test & provides a calibration certificate.	**CALIBRATION** • For equipment requiring a calibration certificate MTO Acquires manufacturers calibration certificate from DEC or If cert. not available then carries out Calibration Test & provide a calibration certificate.
DOCUMENTATION • Equipment Librarian attaches manufactures calibration certificate (if one required) to Registration Form.	**EQUIPMENT RETURNED** • MTO returns tested & labelled equipment to DEC and gets DEC signature on Asset Registration Form 9A.	**EQUIPMENT RETURNED** • MTO returns tested & labelled equipment to DEC and gets DEC signature on Asset Register Form 9A.
EMATS DATABASE • Equipment Librarian updates EMATS and signs Asset Registration Form 9A to confirm.	**DOCUMENTATION** • MTO submits Asset Registration Form 9A, electrical test certificate and calibration certificate to Asset Co-ordinator at Omagh.	**DOCUMENTATION** • MTO submits Asset Registration Form 9A, electrical test certificate and calibration certificate to Asset Co-ordinator at Altnagelvin.
EQUIPMENT RETURNED • Equipment Librarian returns tested & labelled equipment to DEC and gets DEC signature on Asset Register Form 9A.	**EMATS** • Asset Co-ordinator updates EMATS and signs Asset Registration Form 9A to confirm.	**EMATS** • Asset Co-ordinator updates EMATS and signs Asset Registration Form 9A to confirm.
FILING • Equipment Librarian forwards Asset Registration Form & test results to Medical Engineering Manager Altnagelvin for audit purposes.	**FILING** • Asset Co-ordinator files Asset Registration Form & test results locally for audit purposes.	**FILING** • Asset Co-ordinator files Asset Registration Form & test results locally for audit purposes.

Page 1

WHSCT Medical Equipment Asset Registration Process a.vsd JL

Western Health and Social Care Trust

Appendix G

Medical Devices Acceptance & Asset Registration Form

Acceptance and Introduction of Medical Equipment
(PLEASE COMPLETE THIS FORM IN SEQUENCE)

What is the name of the equipment? _____

Has the correct equipment been delivered? _____

What was the delivery date? _____

What is the serial number? _____

Contact Estates for the Asset Registration of the new equipment **Date / /**

What is the Asset ID Number? _____

What is the Purpose of the equipment? _____

Has the equipment been purchased or loaned: _____

Has an Indemnity form been signed? (If loaned) **YES** **N/A**

Who assembled the equipment? _____

Has the overall condition and function been checked? _____

What ward has it been assigned to? _____

Has training on equipment arranged been arranged? **YES** **N/A**

Who provided the training? _____

Is the operating instructions available on Ward: **YES**

Has PDF Operating instructions sent to Intranet administrator **YES** **N/A**

Has Ward Inventory on SharePoint been updated? **YES**

Signed _____ **Designation** _____

Date _____

On completion of ALL aspects of this document the named equipment is ready for use. Completed Form should be passed on to Dedicated Equipment Controller (DEC) for the ward / department.

Notes for completing acceptance form

Name of Equipment – Equipment name e.g. Graseby 3400 infusion pump, Dash 3000 monitor.

Correct equipment delivered – Check delivery docket against delivered equipment (open equipment packaging and inspect equipment)

Delivery Date – This the date that the equipment was delivered as per delivery docket.

Serial Number – Identify unique identification number usually located at the back or the base of the equipment.

Contact Estates for the Asset Registration of the new equipment - Phone estates help desk on 212222 and request a job for the asset registration of the new equipment this will include the electrical safety test and calibration of the equipment if appropriate.

Asset ID Number – Unique Identification number allocated by estates.

Purpose – general description of the intended use of the equipment, eg drug delivery / vital signs monitoring

Purchased or Loaned – Identify if the equipment has been purchased by the trust or on loan by the company.

Indemnity signed by –Form to be completed if equipment is loaned. Forms can be found on the intranet. N/A should only be selected if the equipment is purchased.

Assembled by –Name of person who assembled the equipment if applicable.

Check overall condition and operation function – physically check the condition of the equipment (e.g. outer casing), try operating the equipment in a test condition to ensure that it works.(if appropriate)

Assigned to ward – indicate which ward equipment has been assigned to.

Training on equipment arranged – identify if staff training is required and organise if required. N/A should only be selected if equipment already exists on the ward and previous training has been provided.

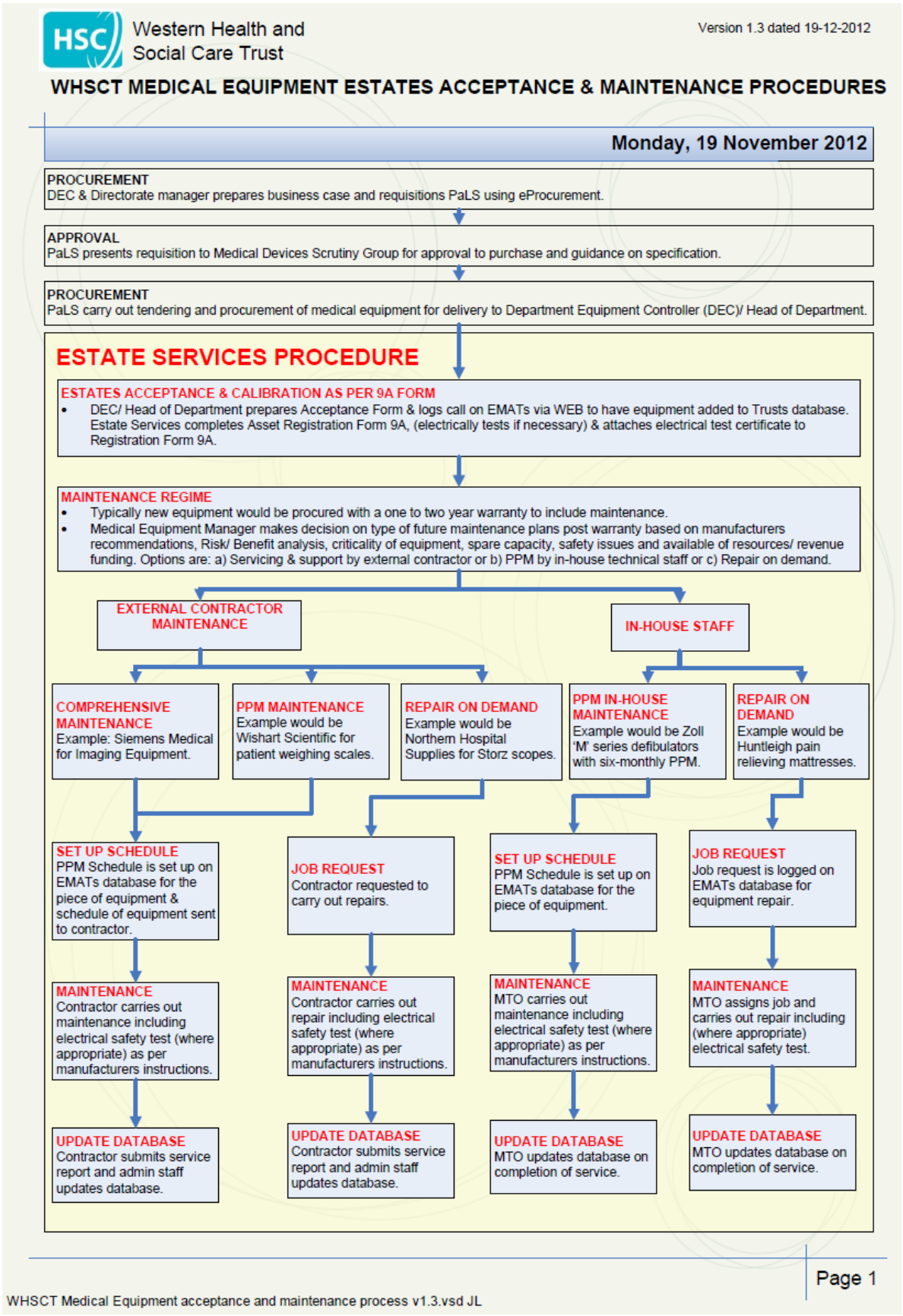
Training provided by – Name of trainer

Operating instructions available on ward – Ensure operating manual for equipment is available to all relevant staff either hard copy or electronic copy this will be made available by the company.

PDF Operating instructions sent to Intranet administrator via E-MAIL – Send pdf to Sharon.dillon@westerntrust.hscni.net. N/A should only be selected if instructions are already available on the Intranet.

Has Ward Inventory on Sharepoint been updated? – Update the ward inventory located in Sharepoint.

Appendix H


Western Health and Social Care Trust
Version 1.3 dated 19-12-2012
WHSCT MEDICAL EQUIPMENT ESTATES ACCEPTANCE & MAINTENANCE PROCEDURES
Monday, 19 November 2012
PROCUREMENT
DEC & Directorate manager prepares business case and requisitions PaLS using eProcurement.
APPROVAL
PaLS presents requisition to Medical Devices Scrutiny Group for approval to purchase and guidance on specification.
PROCUREMENT
PaLS carry out tendering and procurement of medical equipment for delivery to Department Equipment Controller (DEC)/ Head of Department.
ESTATE SERVICES PROCEDURE
ESTATES ACCEPTANCE & CALIBRATION AS PER 9A FORM
DEC/ Head of Department prepares Acceptance Form & logs call on EMATs via WEB to have equipment added to Trusts database. Estate Services completes Asset Registration Form 9A, (electrically tests if necessary) & attaches electrical test certificate to Registration Form 9A.
MAINTENANCE REGIME
Typically new equipment would be procured with a one to two year warranty to include maintenance.
Medical Equipment Manager makes decision on type of future maintenance plans post warranty based on manufacturers recommendations, Risk/ Benefit analysis, criticality of equipment, spare capacity, safety issues and available of resources/ revenue funding. Options are: a) Servicing & support by external contractor or b) PPM by in-house technical staff or c) Repair on demand.
EXTERNAL CONTRACTOR MAINTENANCE
IN-HOUSE STAFF
COMPREHENSIVE MAINTENANCE
Example: Siemens Medical for Imaging Equipment.
PPM MAINTENANCE
Example would be Wishart Scientific for patient weighing scales.
REPAIR ON DEMAND
Example would be Northern Hospital Supplies for Storz scopes.
PPM IN-HOUSE MAINTENANCE
Example would be Zoll 'M' series defibulators with six-monthly PPM.
REPAIR ON DEMAND
Example would be Huntleigh pain relieving mattresses.
SET UP SCHEDULE
PPM Schedule is set up on EMATs database for the piece of equipment & schedule of equipment sent to contractor.
JOB REQUEST
Contractor requested to carry out repairs.
SET UP SCHEDULE
PPM Schedule is set up on EMATs database for the piece of equipment.
JOB REQUEST
Job request is logged on EMATs database for equipment repair.
MAINTENANCE
Contractor carries out maintenance including electrical safety test (where appropriate) as per manufacturers instructions.
MAINTENANCE
Contractor carries out repair including electrical safety test (where appropriate) as per manufacturers instructions.
MAINTENANCE
MTO carries out maintenance including electrical safety test (where appropriate) as per manufacturers instructions.
MAINTENANCE
MTO assigns job and carries out repair including (where appropriate) electrical safety test.
UPDATE DATABASE
Contractor submits service report and admin staff updates database.
UPDATE DATABASE
Contractor submits service report and admin staff updates database.
UPDATE DATABASE
MTO updates database on completion of service.
UPDATE DATABASE
MTO updates database on completion of service.
Page 1
WHSCT Medical Equipment acceptance and maintenance process v1.3.vsd JL

Western Health and Social Care Trust

Appendix I **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

Western Health and Social Care Trust

Appendix J: **Medical Device on Loan to Patients**

MEDICAL DEVICE LOAN FORM

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

Signature of lender: _____

Please return to Ward/Dept: _____

Date returned to Ward/Dept: _____

Signature of recipient: _____

Returned to Equipment Library on: _____

Western Health and Social Care Trust

Appendix K: NIAIC Adverse Incident Report Form HEI No. 98 January 1991

Details of the report:	**Location of the incident:**
Reporting Body: Address : Post Code : Reporter : Position : Tel No : Email : Your Reference:	As Reporter: ☐ Facility/Building: Ward/Dept : Local Contact : Position : Tel No : Email :

NIAIC ADVERSE INCIDENT REPORT FORM

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? ☐ If YES, was the manufacturer or supplier contacted? ☐

Incident Details :

Date of Incident Was there a fatality? ☐ Was an injury caused? ☐

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: **Northern Ireland Adverse Incident Centre, Health Estates, Stoney Road, Dundonald, BT16 1US, Fax 028 90523900, Preferred method e-mail : niaic@dhsspsni.gov.uk** *Version 2008/1*

Appendix L: **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:

	Strength	
	1,000ppm	***10,000ppm***
Chlorine releasing agent Milton or Equivalent	☐	☐
Alcohol 70%	☐	
Other	_____	

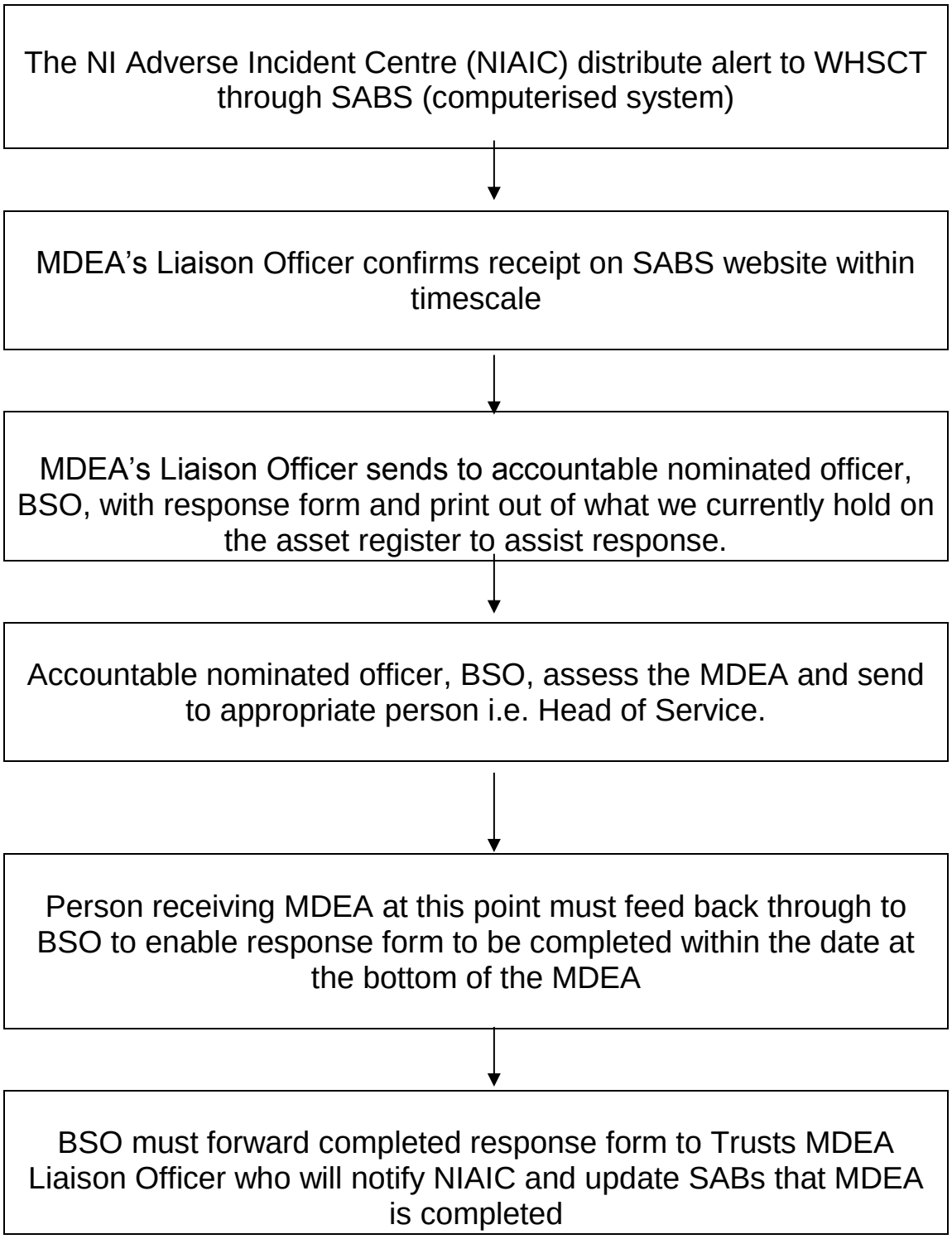
Signature of Member of Staff:_____

Printed Name: _____

Position: _____ **Date**: _____

Appendix M

PROCESS FOR MANAGING MEDICAL DEVICE EQUIPMENT ALERTs and FIELD SAFETY NOTICES



APPENDIX N: WHSCT Equipment Condemnation Notice

Western Health and Social Care Trust

ESTATE MANAGEMENT – EQUIPMENT CONDEMNATION NOTICE

6 **PLEASE COMPLETE IN BLOCK CAPITALS**

7
8 **Asset ID/Barcode**: **Date of condemnation**: **Date of** / / **Cost centre**:
9
10 **Make**:

11 **Model**:

Serial Number:

Description of Equipment ie. infusion pump:

Reason for condemnation (tick appropriate box/es): Enter any additional information in the box below:

1. **Worn out beyond economic repair.** ☐
2. **Damaged beyond economic repair.** ☐
3. **Unreliable……..……** ☐
4. **Clinically obsolete……...** ☐
5. **Technically obsolete……** ☐
6. **Spare parts no longer available…** ☐
7. **More cost effective equipment or clinical service available…….** ☐

Enter details of the location from which the equipment is to be removed:

12 **Building & dept**:
13
14 **Room & room**
15 **no. if applicable**:

Equipment Controller:_____**Signature**:_____

Telephone number: _____ **Date**:_____

Hazardous material (please tick for future action): **Yes** ☐ **No** ☐

Condemned by (name):_____ **Signature**:_____

Date**:** _____

Instructions for distribution:

1. Yellow sheet to Equipment Controller of facility.
2. Pink sheet to your local Estates Services Department.
3. White sheet to remain in book.

Return the pink copy of this form to your local Estates Services Department

APPENDIX O: WHSCT Disposal of Equipment Request

and Social Care Trust

DISPOSAL OF EQUIPMENT - REQUEST

ITEM REF	FULL DESCRIPTION OF ITEMS	QTY	NATURE OF DEFECT	ASSET NUMBER	ESTATES USE ONLY (APPROVED FOR DISPOSAL)		ESTATES USE ONLY (IF DISPOSAL)	
					YES/NO	ACTIONING OFFICER (Initials)	METHOD OF DISPOSAL	ACTIONING OFFICER (Initials)
A								
B								
C								
D								
E								
F								
G								
H								

	Name (Block Caps)		Comments
	Signature		
	Designation		
	Cost Centre No.		
	Location		
	Authorised Signature		
	Date		

APPENDIX P: **Donation Agreement.**

In consideration of the donation of medical equipment and associated consumables ("Goods) to us the "Donee" by the Western Health and Social Care Trust (WHSCT), the Donee acknowledges and accepts the following:

1. The Goods are supplied "as seen". All medical equipment will be donated with a full service history, and decontamination form. Upon receipt of the Goods the Donee shall be deemed to have accepted that the Goods correspond with any description or sample and are of the required quality and fit for their particular purpose.
2. Title to and risk in the Goods shall pass to the Donee once the Goods have left the possession of the Western Health and Social Care Trust.
3. The Western Health and Social Care Trust shall in no way be liable to the Donee or any third party in respect of any representation made by or on behalf of the WHSCT to the Donee, its servants or agents concerning the Goods where such representation is relating to or refers in any way to:
    a. The correspondence of the Goods to any description; or
    b. The quality of the Goods; or
    c. The fitness of the Goods for any purpose whatsoever.
4. All implied conditions or warranties, whether statutory, common law or otherwise, which would apply to the donation of the Goods to the Donee by the WHSCT are, to the extent legally permitted, hereby excluded.
5. No liability whatsoever shall be incurred by the WHSCT in respect of any use of the Goods (including during their storage or transport) by the Donee, its servants or agents or any third party. It is the sole responsibility of the Donee to ascertain the safety and/or fitness of the Goods before use. The Donee is further responsible for the correct use of the Goods according to the relevant manufacturer's instructions and guidelines, and to adhere to any recall request by the relevant manufacturer.
6. Goods which are eventually deemed unusable must be disposed of ethically and comply with the Waste Management Regulations (Northern Ireland) 2006 or, where applicable in accordance with local laws.
7. The Goods must not be sold on to any third party for profit.
8. The donation of the Goods is entirely voluntary and shall not bind in any way the WHSCT to make any future donations to the Donee.
9. The Donee shall indemnify the Western Health and Social Care Trust (WHSCT) against any and all liabilities, costs ,expenses, damages, and losses (including but not limited to any direct, indirect or consequential losses, loss of profit, loss of reputation and all interest, penalties and legal costs calculated on a full indemnity basis, and all other reasonable costs and expenses) suffered or incurred by the WHSCT arising out of or in connection with:
    a. The Donee's breach or negligent performance or non-performance of this agreement
    b. The enforcement of this agreement;

c. Any claim made against the WHSCT by a third party arising out of or in connection with the donation of the Goods or any use which the Donee subsequently puts the Goods to..

Declaration:

I, the undersigned, on behalf of _ Insert charity name_____, accept responsibility and liability for all items described in the "Assets Charity Donation Form". I have read and understand the terms and conditions as outlined above in points 1 through to 9 and agree to be hereby bound by them.

I, ____Insert charity name_____ hereby indemnify the Western Health and Social Care Trust from all and any claims and / or liabilities howsoever arising relating to the agreed equipment donation.

Signed for on behalf of the registered Northern Ireland Charity

Name of Charity: _____

Sign: _____

Print name: _____

Position within the charity: _____

Date: _____

Signed on behalf of the Western Health and Social Care Trust

Sign: _____

Print name: _____

Designation: _____

Date: _____

APPENDIX Q

Western Health and Social Care Trust

ASSETS CHARITY DONATION FORM

NAME & DESIGNATION:	WARD/DEPT:
DIRECTORATE & TEL NO:	COST CENTRE:

EQUIPMENT INFORMATION:

ASSET ID NUMBER (Please insert number in box) ☐ ASSET VALUE IF NOT NIL £ ☐

EQUIPMENT DETAILS: Description: _____

Make/Manufacturer: _____

Model: _____

Serial NO: _____

HAS THE ITEM BEEN CONDEMNED? YES ☐ NO ☐

CONDEMNATION NO: ☐

HAS THE ITEM GOT A FULL SERVICE HISTORY? ☐ YES (MANDATORY)

HAS ESTATES PROVIDED THIS INFORMATION? ☐ YES (MANDATORY)

HAS ASSET VALUE BEEN CONFIRMED BY FINANCE DEPARTMENT ☐ Yes (MANDATORY)

IF ASSET STILL HAS A VALUE HAS RELEVANT DIRECTOR SIGNED OFF ☐ Yes (MANDATORY)

ESTATES AND FINANCIAL ACCOUNTANT FOR CAPITAL, SYSTEMS AND GOVERNANCE INFORMED TO REMOVE ASSET? ☐ YES (MANDATORY)

CHARITY NAME: _____

ADDRESS: _____

CHARITY REGISTRATION NUMBER: _____

PROPOSED DESTINATION OF ITEM: _____

Note: The recipient is not permitted to donate medical equipment within the EU.

LIABILITY:

THE RECIPIENT SHALL BE LIABLE FOR THE NAMED ITEM INCLUDING ANY FUTURE SERVICING AND MAINTENANCE IN LINE WITH THE WHSCT DONATION AGREEMENT DOCUMENT:

RECIPIENT SIGNATURE: _____ DATE: _____

SIGNATURES:

EQUIPMENT CONTROLLER NAME / TRUST STAFF:

SIGNATURE: _____ DATE: _____

RECIPIENT NAME (PRINT): _____

SIGNATURE: _____ DATE: _____