

<b>Medical Devices Policy Practice Guidance Note</b>		
<b>Equipment Acceptance – V05</b>		
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<b>Appendices – listed separate to PGN</b>	
<b>Document No:</b>	<b>Description</b>
Appendix 1	Medical device acceptance form

## 1 OUTLINE

- 1.1 Acceptance Procedure should be carried out in line with current regulations and guidance of the Medicines and Healthcare Products Regulatory Agency (MHRA)
- 1.2 The process can be carried out in three parts.
- 1.3 Aim of the check is to ensure that: -
  - The medical device is delivered undamaged
  - The correct medical device has been delivered and is complete with all relevant manuals, accessories etc.

- Any appropriate safety tests are performed satisfactorily
- The medical device functions correctly and is fit for purpose.
- The medical device details are recorded and a unique inventory number issued via the Medical Devices contact in order to ensure that future medical device management plans can be established

## **2 EQUIPMENT FOR TRIAL, TESTING OR EVALUATION**

- 2.1 Equipment, which enters Cumbria Northumberland, Tyne and Wear NHS Foundation Trust (the Trust) for trial, testing or evaluation, should, in accordance with the NHS Purchasing and Supplies Agency guidance, be indemnified by the supplier.
- 2.2 This **must** be done and confirmed before the equipment is placed into use. An acceptance test should be carried out.

## **3 ACCEPTANCE**

- 3.1 The acceptance test shall apply to all medical devices entering the Trust regardless of ownership, funding source or any other considerations. This includes all equipment: -
- Obtained through normal procurement procedures
  - Purchased by another NHS organisation
  - Donated as a gift
  - Under trial, testing or evaluation
  - Brought into the Trust by staff/service users for their personal use
- 3.2 Certain equipment may be exempt from having to undergo the technical safety checks of the acceptance check process prior to use i.e., electrical safety test. This would be with a manufacturer/supplier that provides equipment on a loan, rental or lease basis and the company has previously agreed to accept responsibility to supply equipment, which is fit for purpose and safe. A record of this equipment would still be recorded through the other aspects of the acceptance test. It may not be necessary to include loan equipment on the medical devices inventory. The Medical Devices contact should be informed of equipment on loan to the Trust.
- 3.3 The acceptance checks will be completed by a clinical technologist when delivery is taken. As part of the acceptance check a safety test will be completed. The Trust has a Service level agreement with a Medical Physics Department to complete this work.
- 3.4 It may be necessary or advantageous to have the supplier's representative present for the whole or part of the acceptance or commission procedure, depending on the terms of the purchase and/or the complexity of the equipment.

#### **4 ACCEPTANCE DOCUMENTATION**

- 4.1 Medical Physics shall ensure that testing and calibration requirements are in place on delivery of the device to the ward/department. An asset ID number will be allocated to this device and an identification sticker applied. Staff accepting this device onto the ward/department will be required to sign the acceptance form. (Appendix 1)  
A copy of the Medical Devices Acceptance form will be stored by the Medical Devices Department.