

Medical Devices Policy Practice Guidance Note		
Maintenance and Repair– V05		
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1 OUTLINE

1.1 Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust (the Trust) uses a range of diagnostic and therapeutic equipment and other medical devices. Under normal circumstances maintenance and repair provision would only be applicable to reusable medical devices. Single use devices are not recorded on the inventory.

2 AIM

2.1 The aim of this practice guidance note is to ensure that: -

- Medical devices remain suitable for their intended purpose
- Medical devices are kept in a safe reliable condition
- All staff involved in the use of medical devices appreciate the importance of an appropriate maintenance and repair programme

- Appropriate maintenance and repairs are carried out by suitably qualified personnel
- Staff who are responsible on a day-to-day basis for ensuring medical devices are maintained understand what is required and the procedures that must be followed

2.2 The supplies department will assist in the selection of organisations to provide maintenance and repair provision to the Trust, through Service Level Agreements (SLA's).

2.3 There are clear guidelines as to the requirements of any organisation (internal or external to the Trust) providing regular contractual services to the Trust are informed as to what is expected of them.

3 MEDICAL DEVICES INVENTORY

3.1 The Trust has a Trust wide inventory of reusable medical devices. This will identify what maintenance provision is required and which organisation, if any is currently contracted to provide that service.

4 MEDICAL DEVICE MAINTENANCE AND REPAIR PRINCIPLES

Refer to (Appendix 1) which is available via the intranet in the Medical Device Page and should be sent to MedicalDeviceADM@CNTW.nhs.uk when completed.

4.1 Correct maintenance and repair is a key element in ensuring that equipment: -

- a) Remains suitable for intended purpose
- b) Is kept in a safe and reliable condition

4.2 Maintenance and repair provision requirements for medical devices should be determined as part of the procurement process and recorded on the medical devices inventory.

4.3 Service Level Agreements (SLA's) for maintenance and repair provision will be co-ordinated through the Trusts' Supplies Department for specific equipment. (Appendix 2)

4.4 Any organisation or person providing maintenance and repair provision must be competent and work within their scope of practice, training and experience. Where appropriate, this will be encompassed in any SLA's.

4.5 Any organisation providing equipment for use within the Trust or for use by Trust staff must provide adequate assurances in respect of the maintenance and repair provision to be provided as part of any SLA or other agreement.

4.6 All maintenance and repair procedures must be recorded and kept on file.

5 WHO PROVIDES THE MAINTENANCE AND REPAIR SERVICE

- 5.1 The Trust mainly uses external service providers to provide maintenance and repair services. These may be manufacturers or independent service providers associated with other NHS organisations.
- 5.2 These will be appointed by SLA's coordinated through the Trust's Supplies Department usually on an annual basis. MedicalAdviceADM@CNTW.nhs.uk will be able to answer enquiries and give advice on maintenance and repairs.
- 5.3 Managing professionals can obtain from the supplies department, details of the service provider and the methods and conditions of contact.

6 RESPONSIBILITIES

6.1 The Trust Board

- 6.1.1 The Trust Board will monitor and seek assurance through The Medical Devices Safety Group that: -
- Resources will be made available to meet any service and repair requirements necessary to ensure the serviceability of the medical device which the Trust owns or is responsible for
 - All necessary action to meet legislative, regulation, guidance and best practice requirements in the maintenance and repair of the medical devices is followed
 - Assurances have been obtained from other organisations who provide equipment for use within the Trust, or by members of the Trust that medical devices are maintained and repaired to a standard which meets legislative, regulation, guidance and best practice requirements

6.2 Medical Devices Safety Group

Will review the provision of maintenance and repair of medical devices within the Trust

6.3 The Trust's Supplies Department

- 6.3.1 The Trust's Supplies Department will: -
- Co-ordinate SLA's for the provision of maintenance and repair
 - Ensure that any maintenance and/or repair provision purchased follows the necessary financial recommendations and guidance

6.4 Maintenance Providers

- 6.4.1 The responsibilities and expectations will where appropriate be detailed in any SLA or other agreement with the provider.

6.4.2 The maintenance provider should: -

- Work within the latest legislative requirements, manufacturer's instructions or guidance from the Department of Health, Medicines and Healthcare products Regulatory Agency (MHRA) or other relevant body
- Provide feedback to the Trust on any implications from changes in legislation or guidance
- Ensure that their staff are competent and are working within their scope of practice, knowledge, skills and experience to provide the maintenance or repair provision being asked of them
- Meet or exceed all the demands placed on their organisation through any SLA between their organisation and the Trust
- Agree mutually convenient times to carry out the maintenance procedures prior to the visit
- Where applicable, report to the reception in the first instance to sign in and obtain a visitor pass, then on to the appropriate senior member of staff
- Carry ID at all times when on Trust sites
- Work in a safe and appropriate manner
- Provide clear and legible documentation, which uniquely identifies the specific item of equipment, details the work carried out and any spare parts used. The documentation must also highlight any defects which remain and give clear and unequivocal guidance on the devices safety, functionality and serviceability
- Use only approved spare parts

6.5 **Managing Professional**

6.5.1 The managing professional should: -

- Ensure any documentation especially relating to maintenance or inspection via third party is clear and legible and available.
- Ensure the equipment is available and in a suitable state for inspection i.e. equipment is complete with all accessories and where necessary is cleaned/decontaminated
- Ensure the equipment does not have any obvious defects
- Immediately report any faults or defects no matter how minor and if necessary, remove the medical device from service

6.6 **All Users**

6.6.1 The user should: -

- Ensure the equipment does not have any obvious defects

- Immediately report any faults or defects to MedcialDeviceADM@CNTW.nhs.uk , remove from service
- Inform an appropriate professional if any equipment is nearing or has passed the date where its safety testing, Planned Preventative Maintenance (PPM), calibration or inspections are due.