NHS
Cumbria, Northumberland, Tyne and Wear
NHS Foundation Trust

Medical Devices Policy Practice Guidance Note **Roles and Responsibilities – V05**		
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Content

Further roles and responsibilities may be outlined within the guidance documents dealing with specific device management topics. All healthcare professionals and support workers are responsible for ensuring they use Medical Devices safely, operate within their professional scope of practice and according to their professional code of conduct.

1 CHIEF EXECUTIVE AND THE BOARD

1.1 The Chief Executive has overall accountability within our organisation for ensuring that arrangements exist for the identification, evaluation and management of all activity associated with the safe use of medical devices.

2 GROUP NURSE DIRECTOR-INFECTION, PREVENTION AND CONTROL

2.1 Will act as the board member with specific responsibility for medical device management.

3 MEDICAL DEVICES SAFTEY GROUP

3.1 This group will monitor, develop and instigate Cumbria Northumberland, Tyne and Wear NHS Foundation Trust (the Trust) strategy with regards to medical devices.

3.2 Will be responsible for ensuring Policy and Practice Guidance notes are kept up to date.

3.3 Will setup processes and procedures to enable the data recorded is as accurate as possible

3.4 This group will lead on the identification of agreed standards for an Approved List of Medical Equipment and Consumables to comply with the Trust's agreed policies and standards of care, which will provide the most cost effective benefits to staff and patients.

3.5 For further information please refer to the terms of reference of the Trust wide Medical Devices Safety Group

4 MEDICAL DEVICE DEPARTMENT (MedicalDeviceADM@CNTW.nhs.uk)

4.1 Will submit orders for medical devices to the supplies department (CNTW Solutions) on the behalf of other departments

4.2 Will update the central inventory on receipt on the device entering the Trust.

4.3 Will process purchase orders requests for medical devices on receipt on an order form Appendix 1

4.4 Will give advice and assistance on decommissioning and disposal of medical devices. Refer to MD-PGN-02

4.5 Will provide assistance in decommissioning and disposal of medical devices. On receipt of a disposal form Appendix 2

4.6 The Medical Device Manager will work closely with Medical Physics, and other specialist departments to ensure their expertise and knowledge is used to

offer guidance to staff that require any information relating to the use of medical devices and those affected by any changes

4.7 Will give advice and support relating to product choice and standardised equipment

5 SUPPLIES DEPARTMENT

5.1 Will coordinate the sale or donation of any medical device in conjunction with other staff as appropriate.

5.2 Will set up maintenance/repair contracts in conjunction with the purchaser and/or other relevant staff

5.3 Will provide advice and guidance in areas such as installation and 'service' requirements where appropriate and will liaise with Medical Physics to offer support to other departments who may be affected by installation or service requirements.

6 FINANCE DEPARTMENT Capital Expenditure -

6.1 The asset register is managed by the Capital Accountant in the Finance Department. Medical devices that cost more that £5,000 (including Vat), should be recorded on the Trust's capital asset register

6.2 If new devices are to be funded from the capital programme a business case should be submitted to the Integrated Business Development Group (IBDG) for consideration. A capital cost centre will be issued by the Capital Accountant for successful bids and the purchase order will be tracked through to payment before the asset added to the capital asset register.

6.3 Capital accountant will be sent a copy of the invoice to the Medical Devices Administrator as routine to assist in the population of the medical devices central inventory.

6.4 The Capital Accountant will visit the department where the asset is held and tag it for capital asset register identification purposes.

6.5 Medical devices purchased from capital expenditure that maybe of a lower value will not be tagged by the Capital Accountant but cross referenced using the medical devices asset ID number.

6.6 The Capital Accountant on a periodic basis will request a copy of the central inventory managed by the Medical Devices Administrator

6.7 The Capital Accountant will keep track of movement of assets and asset disposals.

7 THE SAFETY DEPARTMENT

7.1 Will give advice on all aspects of Health and Safety, relating to medical devices

7.2 Will monitor Health and Safety issues relating to medical devices.

7.3 Will disseminate Safety Action Bulletins (SABs) Device Bulletins (DBs) and other relevant information to appropriate staff and monitor any outcomes through the Central Alerting System.

7.4 Will assist in coordinating any incident where a medical device is involved in a reportable incident

8 THE TRAINING DEPARTMENT

8.1 The Training Department is responsible for coordinating training relating to a range of medical devices.

9 THE ESTATES DEPARTMENT

9.1 Will coordinate routine Potable appliance testing (PAT).

10 THE PRESCRIBING PROFESSIONALS WITHIN THE TRUST

10.1 Will carry out an assessment to identify the patient's needs.

10.2 Will, where necessary involve other staff or external professionals to provide information and/or advice or assistance required.

10.3 Will ensure that only appropriate devices are prescribed.

10.4 Where a prescribed device is already available within the Trust: -

- The risk assessment elements in pre-purchase procedure should be followed and documented
- The appropriateness of the device will be confirmed by physical inspection
- The transfer equipment procedures will be followed
- Information should be documented in the patient's medical notes

10.5 Where a prescribed device is not available within the Trust, the procedure for device procurement (MD-PGN-02) will be followed and an individual assessment made. The assessment should include: -

- Date of assessment
- Details of the assessment including any risk assessments made
- Details of the device selection process and the rationale behind the final choice should be documented

- Who was involved in the assessment process
- A copy of this documentation should be filed in the patient's medical notes

11 PRESCRIBING PROFESSIONALS EXTERNAL TO THE TRUST

11.1 Will ensure adequate training opportunities are made available to the staff within their service area, through either the learning development department or specialist external training Staff are instructed not to use any medical devices that they have not been trained to use.

11.2 Will apply best practice in all medical device management matters.

11.3 Will feedback any issues relevant to Medical Devices Safety Group.

11.5 Will, where appropriate, be involved in the decision for the procurement of new medical devices within their area of expertise.

11.6 Will, where appropriate, be involved in the confirmation and justification of the replacement programme for medical devices within their area of expertise.

12 MANAGING PROFESSIONAL

12.1 The Managing Professional will normally be the Ward Manager, Department Manager, or their Deputy. They are responsible for the day-today management of the Medical Devices within their area and their responsibilities are: -

- To keep a copy of any relevant documentation relating to medical device management.
- To ensure the inventory is kept updated by informing the Medical Devices contact of any changes
- To ensure no new device is used before it has been through the acceptance procedure
- To ensure that any staff unfamiliar with the equipment do not use the equipment unless they are supervised or until they are assessed as being competent, to record completion of training and/or assessment (MD-PGN 06)
- To ensure checks (Safety, Planned Preventative Maintenance (PPM) or inspections) are carried out within the correct time period
- To feedback any information which may influence the purchasing or management of this or similar types of equipment
- To immediately report any faults or defects, no matter how minor, and if necessary, to remove the device from service
- To ensure there is a suitable storage area for equipment when not in use

- To ensure any documentation, especially relating to maintenance or inspection via a third party, is clear and legible
- To ensure that the equipment is available and in a suitable state for day-to-day use, i.e. equipment is complete with all accessories and is, where necessary, cleaned/decontaminated
- To report any adverse incident to their manager and via the Safeguard System immediately after ensuring the safety of patients and staff
- To ensure the operator/user instruction manual and any other relevant information is made readily available to staff. This may not be possible particularly for older equipment and if this is the case, it should be reported to the Medical Devices contact MedicalDeviceADM@CNTW.nhs.uk

13 PROFESSIONAL USER

13.1 For the purposes of this policy, the Professional User is considered to be anyone who uses the medical device as part of their normal working practice. The Professional Users responsibilities are: -

- To ensure that they have either been given adequate competency based training to enable them to use the medical device or can demonstrate, by experience, that they can use the device in a safe and appropriate manner for the purpose for which is was intended
- To have an understanding of all the controls and indicators, including their purpose, what effect they have, how to adjust and/or set them up and what dangers/difficulties they may present. Also, knowledge of the accessories, any consumables and how they are fitted, their purpose, the effect they have, how they are adjusted and/or set-up and what dangers/difficulties they may present: -
- To ensure only appropriate accessories are used
- To ensure the equipment does not have any obvious defects
- To respond appropriately to fault or alarm conditions
- To notify Medical Device Department any faults or defects, no matter how minor, and if necessary, to remove the device from service
- To ensure the equipment is returned to the place it is normally stored when not in use and is left ‘ready to use’
- To ensure that, after use, and on a weekly basis all necessary cleaning/decontamination procedures are carried out and recorded as per IPC-PGN-10 Appendix 5
- To report to the senior manager, any adverse incident immediately after ensuring the safety of the patient, staff and visitors

- To report this incident onto the Safeguard system.

13.2 Professional Users who have received training to enable them to train others, or have demonstrated the ability (experienced training on existing equipment) to train others should: -

- Where appropriate, train other users in all aspects of the equipment to such a degree that they carry out all the normal requirements of a Professional User
- Where appropriate train an End User/Carer in the use of the device to such a degree that they can use the equipment, and if appropriate, clean and store the device and its accessories, correctly and safely.
- Complete training register and return to Training and Development Department.

14 END USER/UNPAID CARER

14.1 For the purpose of this guidance, the end user is considered to be the patient or an unpaid carer – usually a parent, guardian or other individual not employed within the Trust or any other healthcare organisation. The vast majority of the end users may, for a variety of reasons, not have the ability to take on the responsibilities listed below. If this is the case, a professional user or paid carer may undertake these responsibilities on behalf of the end user. This should be documented clearly indicating who is taking on these responsibilities

14.2 The end user (where possible) or unpaid carer, should have sufficient knowledge of all relevant issues relating to the equipment so that they can: -

- Use the equipment in a safe and appropriate manner for the purpose for which it was intended
- Ensure that only appropriate accessories are used
- Ensure the equipment does not have any obvious defects
- Respond appropriately to fault or alarm conditions
- Immediately report any faults or defects onto Safeguard system, to remove the device from service
- Ensure the equipment is returned to the place it is normally stored when not in use
- Ensure all necessary cleaning/decontamination procedures are carried out after use

If the End User cannot satisfy the points in the points above, the device should not be issued