

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Training in the Safe Use of Medical Devices Policy

Effective: January 2008 Reviewed January 2011 Review: January 2013

1. Introduction

1.1 This policy applies to all staff and their managers, who are required to use any type of medical device or therapeutic equipment as part of their work. It defines the importance of ensuring staff are prepared and trained to safely operate/use equipment and that risk management systems are in place and used.

1.2 It is the Trust's aim to ensure all staff using medical devices are competent in their use. To be competent is to be adequately trained, knowledgeable and capable of operating a device in a safe and effective manner. Education and training is essential to ensure that users of medical devices have appropriate knowledge and skills to operate medical devices. Only staff whose training and competence has been established should use any medical device independently.

1.3 For the purpose of this policy the term "Medical Device" encompasses devices as defined in MHRA Bulletin 17 "Medical Devices and Medicine Products" (amended April 2006) and can be summarised as:

"Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means".

1.4 This policy is aimed to support safe practice and does not constrain your clinical autonomy whatsoever, your own clinical judgement is to be exercised at all times and as such, clinical need/ emergency situations may over ride this policy. In exercising your own professional judgement, any alteration from this policy must be noted on an incident form. This is important for legal accountability.

2. Policy scope

- 2.1 The Newcastle upon Tyne Hospitals NHS Foundation Trust aims to ensure that all clinical staff who operate diagnostic or therapeutic medical devices can do so in a safe manner.
- 2.2 The Trust expects that all permanent clinical staff, including doctors in training should adhere to the principles of this policy.

3. Policy aim

To ensure that all staff operating diagnostic or therapeutic equipment can do so in a safe and effective manner.

4. Policy Objectives

- Accountability – that adequate records are maintained at Directorate / Department level to account fully for training of all staff.
- Training – that all staff are made aware of their responsibilities and are shown to be competent through generic and specific training programmes.

5. Roles and Responsibilities

All users of Medical Devices are responsible for:

- Being familiar with their responsibilities under this policy and complying with them
- Ensuring their own competence in the use of an item of equipment and have successfully completed training where necessary to use the equipment independently
- Ensuring that on the completion of competency assessment, this information is recorded on the Trust Medical Devices training recording system.

Adhering to the following principles before using any medical equipment:

- Only using equipment identified on the Trust Medical Devices Inventory
- Do not use equipment unless they trained to do so
- Identify their training requirements with line manager/supervisor
- Have completed agreed practice and be deemed competent through self assessment or by a supervisor/trainer to operate independently
- Always visually inspect the equipment for signs of damage prior to use
- Ensure any accessories and or disposables required are recommended by the manufacturer
- Know where the user manual / instructions are located.

All managers of users of medical devices are responsible for:

- Ensuring that all equipment used is recorded on the Trust inventory
- Agreeing with individual members of staff which equipment from the inventory they are expected to use and the process for training and competency assessment, including frequency of updates.
- Ensuring that training is made available for all users of devices where training is necessary, and that all equipment users are properly trained and competent
- Ensuring that users complete competency records for appropriate medical devices.

The Medical Devices Steering Group is responsible for:

- Developing, implementing and monitoring compliance with this policy to ensure best practice
- Developing action plans where there is limited assurance of compliance with the policy.

6. Training

- 6.1 The ward/department manager is required to compile an inventory of medical devices used in their area of responsibility. Assistance to compile this inventory can be obtained by: Clicking on “Log Estates and IT Service Requests” on the Trust intranet page, then clicking on “Log / Query Estates service desk jobs”; enter the department telephone number and select “Show Assets for your Department” from the list. This inventory must be reviewed annually and or when new equipment/devices are introduced into their area of responsibility. An example of documentation used to record this can be found as Appendix 1, alternatively the updated printed list from the intranet may be used.
- 6.2 A training needs analysis should be undertaken annually to identify the training needs of all staff in relation to medical devices within the directorate. This should include training updates as well as training on new devices. This training needs analysis should be carried out by directorate/department managers or nominated deputy. Consideration must be given to ensure competencies set meet individual staff needs. Personal Learning plans can be used to assist this process – see example attached as Appendix 2.
- 6.3 In the event of the appropriate training being unavailable from any source, this must be raised as a risk and included on the risk register. Until this issues has been resolved or rectified the equipment must not be used.
- 6.4 No medical equipment shall be used clinically and independently unless the operators, who use the device(s) have received appropriate training, which includes pre use checks to be made prior to the use of any piece of kit. This policy is aimed to support safe practice and does

not constrain your clinical autonomy whatsoever, your own clinical judgement is to be exercised at all times and as such, clinical need/emergency situations may over ride this policy. In exercising your own professional judgement, any alteration from this policy must be noted by completing an incident form on Datix.

- 6.5 Department managers (or nominated deputies) must identify training and assessment needs at appointment, local induction and as part of annual reviews.

7. Competency Statements

- 7.1 It is essential that all practitioners using items of medical equipment independently are deemed competent in the safe and effective use of the equipment and can demonstrate this to their manager.
- 7.2 Training should be provided by a practitioner competent in the functions and operations of the device. An example of a competency statement is attached as Appendix 3.
- 7.3 Where a competency statement does not exist, expert users within areas can develop the statement for assessment, using the competency statement template on the EME Loan Library intranet site. This competency statement must then be posted on the EME Loan Library intranet site.
- 7.4 Should a member of staff be unable to demonstrate competence, their ward/department manager must arrange re-training before the individual can operate the medical device in a clinical environment independently.
- 7.5 Staff beginning employment with the Trust must complete the Trust corporate induction program where the following medical device related topics will be covered:
- Infection Control
 - Fault Reporting
 - Clinical Risk
 - Competency Assessment
 - Reporting procedure for adverse incidents
 - Safe lifting & handling
- 7.6 When a new medical device is introduced into an area, staff should receive training or instruction competency before using the equipment unsupervised. All training and competency assessment information should be recorded on the Trust Medical Devices Training recording system.
- 7.7 Reference should be made to the [Management of Medical Devices Policy](#).

8. Monitoring

- 8.1 Compliance of Directorate activity will be monitored by the Medical Devices Steering Group. The Medical Devices Steering Group will monitor the processes for identifying which staff are authorised to use the equipment, process for determining training requirements and updates and processes to ensure that identified training needs are met. The Medical Devices Steering Group will provide an Annual update on training activity to the Trust Education Board.
- 8.2 All incidents, accidents or near misses, related to the use of medical devices should be reported on the Datix system. The Clinical Governance and Risk Department will provide quarterly reports on themes and trends to the Medical Devices Steering Group.

Bibliography:

- NHSLA “Risk Management Standards for Acute Trusts”, published by the NHS Litigation Authority (January 2010)
- MHRA Devices in Practice (August 2008)

Author: Chair of Medical Devices Steering Group

Personal Learning Plan

Name:		Department:		Date:	
What do I want to learn?	What will I do to achieve it?	What resources/ support will I need?	How will I know I have succeeded?	Target Date	Review



HIGH RISK

Competency Statement ABBOTT 'PATROL' FEEDING PUMP	SELF /PEER ASSESSMENT
Surname:	Forename(s):
Title (Mr/Mrs/Miss/Dr etc):	Personal Number (stated on wage slip):
Job Title/Designation	
Dept/Directorate & Ward/Unit:	Extension No.:

Self-verification/Peer assessment of competence is undertaken by assessment against the following statements:
 These statements are designed to indicate competence to use this device. Responsibility for use remains with the user, so if you are in any doubt regarding your competence to use the device, you should seek education to bring about improvement. Various methods including, self-directed learning, coaching & formal training may be initiated. (Consider local resources, product operating manual, the intranet <http://intranet/emeloan/default.html> & discussion with colleagues or the Medical Devices Trainer)

Carry out an initial assessment. You must be able to answer, "yes" to all the questions before considering yourself to be competent .If you are not competent, instigate learning & then repeat self-verification.
Peer assessment will involve the practitioner demonstrating competence against the following statement to an experienced colleague who has already undergone assessment

Questions to ask yourself:	Initial assessment date:	Final assessment date:
Are you safe using this device? Do you know the following?	Yes/No	Yes/No
1. Demonstrate an understanding of the A&P of the human body relating to enteral feeding and rationale for use of feed and pump?	1. Yes/No	1. Yes/No
2. Collect the correct consumables for use with the pump?	2. Yes/No	2. Yes/No
3. Connect the pump to power and turn on?	3. Yes/No	3. Yes/No
4. Demonstrate connection and run through of administration set?	4. Yes/No	4. Yes/No
5. Clear the 'volume' and 'set' the 'dose' and 'rate' limits?	5. Yes/No	5. Yes/No
6. Safely commence the feed regime, with explanations to patient?	6. Yes/No	6. Yes/No
7. Discuss 'warning codes' that may occur and rectification of these?	7. Yes/No	7. Yes/No
8. Explain the procedure for running on battery power and how long a fully charged battery lasts?	8. Yes/No	8. Yes/No
9. Demonstrate correct cleaning and safe storage of this pump?	9. Yes/No	9. Yes/No

Statement: Having answered "yes" to all the questions above & taken into account my personal assessment of my competence with the product, I declare that:
 I am competent to use this product without further training

Signature: _____ : Date: _____

I require further training before I can use this product in a competent manner.

Signature: _____

Indicate how you plan to meet your learning needs:

Peer Assessment Statement: I have peer assessed.....and they are competent to use this product without further training.

Signature: _____

Print Name : _____ Date: _____

Keep this form in your portfolio or training record. Ensure that your manager has seen the form & entered details of your competence in their records

THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST
IMPACT ASSESSMENT – SCREENING FORM A

This form must be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

Policy Title:	Training in the safe use of medical devices policy	Policy Author:	Education Development Manager
		Yes/No?	You must provide evidence to support your response:
1.	Does the policy/guidance affect one group less or more favourably than another on the basis of:		
	• Race	No	This policy does not discriminate against any race, ethnic origin, nationality, gender, culture, religion or belief, sexual orientation, age or disability.
	• Ethnic origins (including gypsies and travelers)	No	
	• Nationality	No	
	• Gender	No	
	• Culture	No	
	• Religion or belief	No	
	• Sexual orientation including lesbian, gay and bisexual people	No	
	• Age	No	
	• Disability – learning difficulties, physical disability, sensory impairment and mental health problems.	No	
2.	Is there any evidence that some groups are affected differently?	No	
3.	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	No	
4.	Is the impact of the policy/guidance likely to be negative?	No	
5.	If so can the impact be avoided?	N/A	
6.	What alternatives are there to achieving the policy/guidance without the impact?	N/A	
7.	Can we reduce the impact by taking different action?	N/A	

For advice on answering the above questions please contact Helen Lamont, Deputy Director Nursing & Patient Services, or, Christine Holland, Senior HR Manager. On completion this form must be forwarded electronically to Steven Stoker, Clinical Effectiveness Manager, (Ext. 24963) steven.stoker@nuth.nhs.uk together with the procedural document. If you have identified a potential discriminatory impact of this procedural document, please ensure that you arrange for a full consultation with relevant stakeholders to complete a Full Impact Assessment (Form B) and to develop an Action Plan to avoid/reduce this impact; both Form B and the Action Plan should also be sent electronically to Steven Stoker.

Name of Person responsible for completion of this form

and who else has been involved in the consultation process: Anne Marie Troy- Smith Education Development Manager .Consultation & review by the Medical Devices Steering Group. Also consulted with Karen Giles – Head of Training.

Date of Completion: 14th Nov 2008.....Action Plan due (or Not Applicable): Not Applicable

(If any reader of this procedural document identifies a potential discriminatory impact that has not been identified on this form, please refer to the Policy Author identified above, together with any suggestions for the actions required to avoid/reduce this impact.)