University Hospitals of Derby and Burton NHS Foundation Trust

TRUST POLICY AND PROCEDURE FOR THE COMPETENCY AND TRAINING REQUIREMENTS CONNECTED WITH MEDICAL DEVICES

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	5	July 2014	R Turner & M Cannell	Review
	6	September 2017	R Turner & M Cannell	Review
	7	November 2020	R Turner	Joint UHDB Policy

Intended Recipients: All Trust Staff using Medical Devices within the influence of University Hospitals of Derby and Burton NHS Foundation Trust	
Training and Dissemination: Dissemination via the Trust Intranet. Medical device training delivered by Trust authorised product manufacturer input, Trust corporate (Equipment Library Clinical Equipment Trainers CET) and department link trainers	
To be read in conjunction with: Medical Devices - Management - Trust Policy and Procedure, Change in Clinical Practice - Trust Policy and Procedure	
In consultation with and Date: Medical Devices Committee (MDC) Sept 2006, H & S Committee 2003, Risk Management Committee 2003, MDC (Training Sub-group) and MDC October 2011. Review MDC 2017	
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Contact for Review	Medical Devices Training Co-ordinator
Executive Lead Signature	Magnus Harrison
Approving Executive Signature	Magnus Harrison

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TRUST POLICY AND PROCEDURE FOR THE COMPETENCY AND TRAINING REQUIREMENTS CONNECTED WITH MEDICAL DEVICES

1. Introduction

The increasing complexity of modern healthcare management has brought with it great risks, namely in the form of the misuse of the equipment required to deliver it.

The processes to deliver these complicated investigations or therapies often require an in-depth knowledge and skill to ensure best outcomes for the patients. This Policy indicates the processes for identifying the levels of training and assessment needed for the variety of equipment held on University Hospitals of Derby and Burton NHS Foundation Trust's (the Trust) lists (See Appendix 1).

The Trust currently has tens of thousands of devices on its inventory, to make this manageable they have been further categorised into 100 plus sub-groups to allow for assessment of the inventory of all equipment used at Appendix 2.

2. Purpose and Outcomes

In order to assist in the management of risks within the organisation, the Trust needs to be assured that it is in a position where only practitioners assessed as appropriately competent will operate Medical Devices. The objective of this Policy is to ensure the necessary arrangements are in place to achieve this.

This Policy supports the Trust and professionals working within it, to better meet their respective moral, professional and legal duties of care, with respect to their own professional body's codes of conduct, Health and Safety Law, Care Quality Commission: Essential Standards of Quality and Safety (2012), Section 20 of the Health and Social Care act (2008), and standards Outlined by EU Regulations for Medical Devices and the Medicines and Healthcare Regulatory Agency

It identifies:

- Links to the Trust inventory of diagnostic equipment
- The process for identifying which permanent staff are authorised to use equipment
- The process to determine the training required and the frequency of updates
- The process for ensuring that the training needs are met.

This Policy also supports the management of the NHS Commissioning Board Special Health Authority, and Medicines and Healthcare Regulatory Authority (MHRA) alert systems, allowing for a co-ordinated and corporate approach to some of these notices.

This Policy excludes Pathology and Radiology as they complete competence as per UKAS accredited process (see Appendix 5)

3. Definitions Used

Medical Device

For the purpose of this Policy a Medical Device is considered to be:

- Equipment used in the diagnosis / treatment of disease, or the monitoring of patients and is serviced/maintained via Clinical Engineering
- Equipment used in life support

In day to day use the terms medical 'device' and 'equipment' are often interchangeable. This Policy applies primarily to re-usable electro-mechanical medical equipment.

'Ordinary' or 'Domestic' type equipment used in the assessment of patients is not deemed as a Medical Device; therefore competency records are not required under this Policy. However, competency of the equipment will need to be included in the learning process of this patient assessment.

Training and Competency

To be competent is to be adequately qualified / trained and proficient to safely operate the Medical Device.

- Training is generally instruction of a practitioner in the operation of a Medical Device and the clinical applications. This includes reference to identification of faults and methodology for corrective action. The level of competency / training will be directly related to the risk category
- Competency is considered as a verified assessment and recorded by other recognised competent individuals, preferably a Link Trainer / Assessor, only being valid if recorded upon the Trusts Central Database (Appendix 6)

Practitioner

For the purpose of this Policy a practitioner is considered to be:

- Clinical staff setting up a Medical Device prior to operation
- Clinical staff involved in operating a specific Medical Device
- Clinical staff involved in testing / calibrating and / or maintaining equipment prior to or during the operation of a Medical Device.

Loan equipment

There are two varieties of loaning that occur in the Trust. Firstly there is the situation where equipment owned by ourselves is 'loaned out' to other organisations / patients / carers but ultimately is returned to us. Secondly there is the situation where equipment is 'loaned in' that is actually owned by another organisation.

Training Needs Analysis

This is a local assessment of devices used within that area, it identifies staff grades that should be competent, and how that competency should be gained, with an indication of how frequently it should be reassessed (Appendix 4).

4. Key Responsibilities / Duties

4.1 Individual Staff

Staff must be aware that they have an individual responsibility to achieve and maintain their competency, with regard to Health and Safety Law, professional accountability and Trust Liability.

They should recognise their own limitations, with regard to using equipment, and appreciate the issue of review dates once competency has been stated. Monitoring of these points with their respective managers could be via annual performance review, recording this information on the Trust's central database is required for recognition.

4.2 Department Co-ordinating Staff (Link Trainer / Assessor)

All wards and departments have a local equipment training co-ordinator, which is the senior ward sister / department head. This role can be delegated as a development opportunity to other staff in the department, but the responsibility for the compliance remains with the department head.

This co-ordinator role is responsible for ensuring that:

- All staff have undergone appropriate competency assessments and attended the relevant training courses for equipment used in that area. (Appendix 6)
- All competencies are up to date
- All competency records are complete and up to date. Verified Assessment Forms may be used (Appendix 3)
- All competencies are reported to the Equipment Library (Patient Safety) for entry onto the Trust Database
- Their respective area's "Training Needs Analysis" is current, valid and fit for purpose. (Appendix 4).

4.3 Non-Trust Staff

All staff working as members of this Trust - providing service in areas managed by this Trust, e.g. Locum, Agency, Academic staff, and Students will adhere to this Policy.

4.4 Divisional Leads

Each clinical division will have at least one nominated individual at Divisional level which will;

- Represent the Division at the Medical Devices Product User Group (MDPUG)
- Provide Action Plans and updates from their divisional subgroups / forums to meet identified problems, or reporting positive outcomes
- Identify within the Corporate and division groups' terms of reference, specifically identifying the manner and frequency of reports
- Provide information / feedback to their respective divisional reporting systems and groups from the Trust Medical Devices Leads.

4.5 Equipment Library Manager and Clinical Specialist (Medical Device Safety Officer MDSO)

Is the Trusts appointed Medical Devices Safety Officer. Manages the Medical Devices Training Team, Chairs the Medical Devices Product User Group and Medical Devices Operational Group, reporting to the High Level Medical Devices Group.

4.6 Equipment Library Senior Trainer and Specialist (Lead Medical Devices Training Co-ordinator LMDTC)

Co-ordinates and manages the introduction of new devices and technology through links to Purchasing and Commissioning, also has powers to quarantine equipment until acceptable training levels are attained and registered. The Lead Medical Devices Training Co-ordinator will review the progress on all aspects of the policy as part of the regular reports, reports to the MDSO and is responsible for reporting at Trust level (at MDPUG, Education Training and Development Group ETD).

4.7 Corporate Clinical Equipment Trainer / Officer (CET)

The CET is responsible for the monitoring and reporting of compliance.

Assists LMDTC to co-ordinate and facilitate the introduction of new devices and technology across the Trust.

Provides regular training and competency assessment sessions in support of the above and is responsible for the auditing of departmental and individual's competency records, reporting directly to LMDTC and Clinical Governance Facilitators (CGF). The CET is responsible for training and supporting Link Trainers / Assessors.

The CET is also responsible for reviewing and updating corporate training packages / material and Intranet pages.

4.8 Trust Executive Medical Director

This is the Executive lead for medical device management within the Trust. This post receives reports on compliance from LMDTC and CET, on behalf of the Trust board, in the MDPUG forum, these will be provided quarterly as a minimum, but every two months would be considered the norm.

MDSO will refer issues of significant risk / concern directly to the Executive Medical Director for information and support of any remedial action plans.

5. Managing Medical Device Competency (CQC Outcome 11:Reg 16)

To manage the risks of equipment utilisation this must be appropriately assessed to enable reasonable and targeted steps to be undertaken. Use of equipment outside of these requirements constitutes a hazard to our patients (and staff) welfare, and as such opens the individual(s) involved to disciplinary action.

5.1 Risk Categorisation of Equipment on the Inventory

Categorisation of the medical equipment (registered upon the Clinical / Medical Engineering Department's database – AIMS/e-Quip: EU/UK Medical device regulations 4.8): is via risk assessments (Appendix 1) performed in conjunction with the Medical Devices Training Co-ordinator, Clinical Equipment Trainers and any Trust experts. This is on introduction of new equipment to the Trust, or by request of Department Co-ordinating Staff. This information is published through the Medical Devices Intranet pages.

5.2 Process for Identifying Which Staff are Authorised to use Equipment Identified on the Inventory (EU regulations for MDR and IVDR 3.5.2)

Working with the Department Co-ordinators, a training needs analysis of devices, both available and required for department function will be performed by the CET, every two to three years to identify the appropriate training and assessment for the staff in those areas to receive; this will identify grades and frequency of assessment if different to Trust standards (Appendix 4).

The details of the Training Needs Analysis will be held on a central database, and the responsibility for these assessments lies at departmental level but requires ratification and recognition by the CET and LMDTC, maximum period between re-assessment is considered two to three years. Assessment documentation may change over time, thus a record of old assessments will be held corporately.

5.3 Staff Training and Assessment Requirements

As a result of the two previous processes all equipment will be classed as extreme, high, medium or low risk. For each category staff will hold competency that will require reassessment.

For each category a maximum reassessment period has been identified.

Extreme: **3 years Max**
High: **5 years Max**
Medium: **8 years**
Low: **10 years**

Reassessment can be identified as being required more frequently if equipment is used infrequently (i.e. Defibrillators), users are assessed annually.

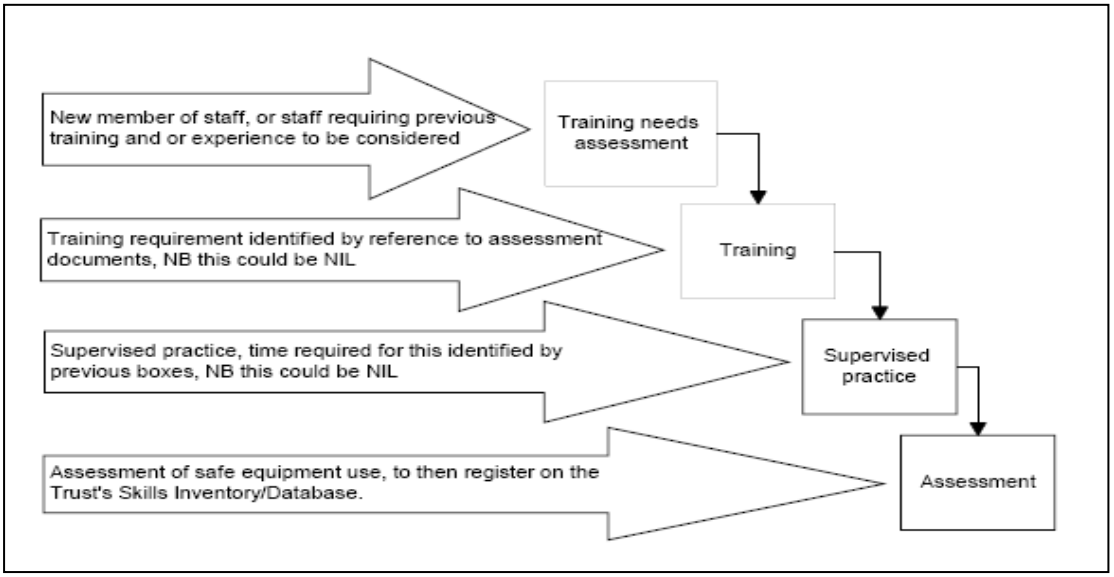
Reassessment can also be identified as being required more frequently for different areas by the LMDTC and CET in discussion with ward sisters / dept. lead (i.e. Surgery day case ward use syringe drivers infrequently, whereas Intensive Care use them frequently). This will be shown on each area's Training Needs Analysis.

Reassessments prior to expiry are not discouraged; they may be used if staff are deemed to need reassessment i.e. return to work, disciplinary proceedings or improving on good practice in demanding areas.

Staff groups / individuals equipment competency checks are in the form of an assessment undertaken by local equipment training co-ordinators requiring a level of verification. Allowing,

where a deficit is detected, a competency / training package to be undertaken (summarised below).

New but experienced staff will be able to undertake a fast track version of the competency / training package, whereas, new but inexperienced staff members wishing to use any of the equipment, will be required to complete full competency / training packages.



To be competent is to be adequately qualified / trained and proficient to safely operate the Medical Device.

- Training is the instruction of a practitioner in the operation of a Medical Device. This includes reference to identification of faults and methodology for corrective action. The level of competency / training will be directly related to the risk category.
- Competency for all Medical Devices, is considered as a verified assessment and recorded by other recognised competent individuals, preferably a Link Trainer / Assessor - only being valid if recorded upon the Trusts Central Database.

Self-assessment is not supported at the Trust

Records of competence are completed at, and may be kept at ward level. All competencies must be submitted to the Equipment Library by an authorised electronic notification. i.e. from the local coordinator or team leader (See Appendix 6). Records are then added to the individual's records within the Trust's database These records are to be audited by the CET for departmental compliance at least once every six months, depending on the departments historical compliance;

- Compliance of >95% = re-audit 6 months
- Compliance of >75% = re-audit 3 months
- Compliance of <75% = re-audit 1 month

All results to be reported by the CET directly to the LMDCT and CGF's.

5.4 User Error Incidents

Individuals involved in an incident where the use of the device is demonstrated as incorrect would need to receive re-training and re-assessment. If a High or Extreme risk device is involved the individual is to cease using the device until re-assessment is complete.

5.5 Escalation Procedure

Training

Non-attendance at booked Central Training is to be escalated to the line manager of the staff not in attendance. Line Manager is then to re-book the staff onto the Training.

Persistent non-attendance (3 or more) will be escalated to the area Matron and the Divisional CGF.

Compliance

Non-compliance (<75%) of Departmental Competency Records is to be escalated to the area Matron and Divisional CGF.

Persistent Non-compliance is to be escalated to the Senior Management Team and Head of Patient Safety.

5.6 New Equipment

When new equipment enters the Trust (this includes new technology and different makes / models to those previously found in the Trust) after meeting the necessary needs of the Change in Clinical Practice Policy the department / staff will need to consider its risk banding. This is so that they are aware of the degree of competency / training that would be required i.e. for extreme / high-risk pieces of equipment a higher / more tightly defined level of competency / training would be applicable. Any corporate level risk assessments will be registered upon the central list.

5.7 Quarantine Process

A holding / quarantine period will apply to all applicable new equipment entering the Trust (this is in line with the formal acceptance procedures). It will be clearly marked as quarantined. The process of quarantine will vary with the device in question, ranging from the device(s) being held away from the clinical areas, to strict use and user guidelines.

All quarantine processes will be negotiated with the LMDTC; no device will be released from quarantine until these formally agreed criterions have been met. This allows the Trust to ensure that all devices are used by or under direct supervision of an appropriately competent and trained practitioner (CQC Outcome 11:Reg 16).

This process is intended to encompass all levels of staff within this Trust.

5.8 Loan Equipment

The quarantine process will apply to Equipment Loaned into the Trust. Direct supervision of the Trust user by an authorised representative of the loaning agency will generally be required.

The loan of equipment from the Trust to individuals / other organisations puts the responsibility on the authorised referring Professional to ensure the users have a valid understanding of the safe use of the device, including emergency contact numbers (if appropriate) and have competent written instructions, to enable correct use and simple trouble shooting.

5.9 Training Events

These may be organised locally or centrally, they need to be agreed and monitored via the CET, specifically for relevance, consistency and for validity.

5.10 Records of Competency

These must be submitted to the Equipment Library / Patient Safety to be registered upon the Trusts Central database to be considered valid, the original signed copies may be held by the department where the staff member is based(See Appendix 6). Trust approved documentation is available on the Trust Intranet for these assessment records (see Appendix 3). The central records are to be audited by the LMDCT / CET for departmental compliance at least once every six months, depending on the department's historical compliance. These will be made available to the appointed Divisional Lead for Medical Devices Training. Notification is either by an electronic Competency Reporting Form, part of Medical devices web pages or by email to the Equipment Library administration, for input.

6. Monitoring Compliance and Effectiveness

Monitoring Requirement :	Compliance is reliant upon the efforts of the trainers and assessors, their diligence in the observation of their colleagues requires recording on the Trust data system. Compliance requires a "Training Needs Analysis" to be available for each area, identifying equipment used upon that area and how competence is achieved and measured (see Appendix 4)
Monitoring Method:	A report will be produced from this system each time the CET / LMDCT completes an audit of departmental records. Each report will display overall department compliance and identify which individuals require competency assessment and submission of records. These reports will be made available to the Team leader, and Link Trainer / Assessor of each department audited. An overall accumulative formal report will be produced from these results and will be reported directly to the Clinical Governance Facilitators and Divisional Lead for sharing at MDPUG. Failing Departments will be provided with guidance and support from the CET and will be audited monthly until compliance >75%
Report Prepared by:	LMDTC and CET
Monitoring Report presented to:	MDPUG
Frequency of Report	6 monthly

7 References

The Provision and Use of Work Equipment Regulations 1998. SI 1998/2306: London, HMSO (Available from http://www.opsi.gov.uk/si/si1998/19982306.htm)

The Medical Devices Regulations 2002. S.I. 2002/0618: London, HMSO. (Available from http://www.opsi.gov.uk/si/si2002/20020618.htm)

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Medicines and Healthcare Regulatory Authority (MHRA) Medical Device alerts, (Available from http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/MedicalDeviceAlerts/index.htm)

Managing Medical Devices: Guidance for healthcare and social services organisations - April 2015 Medicines and Healthcare products Regulatory Agency, London

NHSLA Acute, Community, Mental Health & Learning Disability and Independent Sector Standards (2013/14) NHSLA, London. (Available from http://www.nhsla.com/safety/Documents/NHS%20LA%20Risk%20Management%20Standards%202013-14.pdf)

Care Quality Commission, Regulation 15: Premises and equipment (2014) CQC, London, (Available from https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-15-premises-equipment#full-regulation)

Care Quality Commission, Essential standards of quality and safety (2010) CQC, London (Available from https://services.cqc.org.uk/sites/default/files/gac_-_dec_2011_update.pdf)

The Standards for Better Health (2004). Standard C4(b).The Health Care Standards Unit. (Available from http://www.hcsu.org.uk/index.php?option=com_content&task=view&id=197&Itemid=109)

Learning from patient safety incidents, NHS Improvement (Available from https://improvement.nhs.uk/resources/learning-from-patient-safety-incidents/)

Appendix 1

Risk assessment of equipment for training

EQUIPMENT TRAINING RISK ASSESSMENT TOOL

Equipment being risk assessed

When applying the risk assessment process to equipment the following principles should be assumed:

- That the equipment is safe to use
- That the practitioner (doctor, nurse, midwife, PAMs, ODP, health support worker) who will use the equipment possesses an understanding of the said medical device in relation to the rationale for use, including contraindications and outcomes. ***If the individual does not have the outlined understanding (such as newly qualified practitioner, training practitioner, or established practitioner new to speciality), responsibility for addressing the knowledge deficit falls with the senior / supervising clinician. This will be reflected in the individuals personal development plan and as the initial criteria within all training packages***
- That although the practitioner possesses the stated understanding they have not received training for this piece of equipment

LIKELIHOOD			*CONSEQUENCE*		
Will occur on every occasion.	Certain	5	Multiple deaths / closure of the hospital / huge financial loss	Catastrophic	5
Is expected to occur in most circumstances.	Expected	4	Death / closure of a service / major financial loss	Major	4
Could occur in many circumstances	Likely	3	Major injury / adverse health outcome / significant long tern service disruption / high financial loss	Serious	3
Could occur occasionally	Unlikely	2	Moderate injury / adverse health outcome / significant short term disruption to service / moderate financial loss	Moderate	2
Do not expect it to happen, but it is possible	Rare	1	Minor injury / adverse health outcome / some disruption to service / significant financial loss	Minor	1

Likelihood	Consequence				
	Minor 1	*Moderate* 2	*Serious* 3	*Major* 4	*Catastrophic* 5
Certain 5					
Expected 4					
Likely 3					
Unlikely 2					
Rare 1					

E	Extreme risk, immediate action required	*H*	High risk, action planned immediately, taken within one month
M	Moderate risk, action planned within one month, taken within three months	*L*	Low risk, action planned within three months, reviewed within 1 year

Appendix 2

Risk assessed equipment list

Device type	Likelihood	Consequence	Score	Risk category
Fetal Heart Monitor	3	5	15	E
Defibrillator	3	4	12	E
Intra Aortic Balloon Pump	3	4	12	E
Resuscitator	3	4	12	E
Syringe Driver	3	4	12	E
Volumetric Pump	3	4	12	E
X-ray Contrast Injector	3	4	12	E
Electrosurgical Diathermy	3	3	9	H
12 Lead ECG	3	3	9	H
Surgical Lasers	3	3	9	H
Anaesthetic Machine	2	4	8	H
Autologous Transfusion Device	2	4	8	H
Dialysis Machine	2	4	8	H
Neonatal Incubator	2	4	8	H
Patient Moving Equipment	2	4	8	H
Pneumatic Tourniquet	2	4	8	H
Ultrasonic Coagulator	4	3	9	H
Ventilator	2	4	8	H
Fetal Heart Doppler	2	3	6	M
Suction - Electronic	2	3	6	M
Major Radiotherapy Equipment	2	3	6	M
Suction - Gas	2	3	6	M
Cleaning/Disinfecting System	2	2	4	M
Enteral Feed Pump	3	1	3	M
Function Testing	2	2	4	M
Patient Observation Monitoring	3	2	6	M
Point of Care Testing	3	2	6	M
Respiratory Advanced	2	3	6	M
Respiratory Basic	2	2	4	M
Ultraviolet Therapy	2	2	4	L
Tables & Couches	1	3	3	L
Other Lighting - Clinical	1	3	3	L
Medical Gases and Flowmeters	1	3	3	L
Ophthalmic Equipment	1	3	3	L
Plaster Cutting	3	1	3	L
7 bar Theatre Air Tools	2	1	2	L
Beds and Mattresses	1	4	4	L

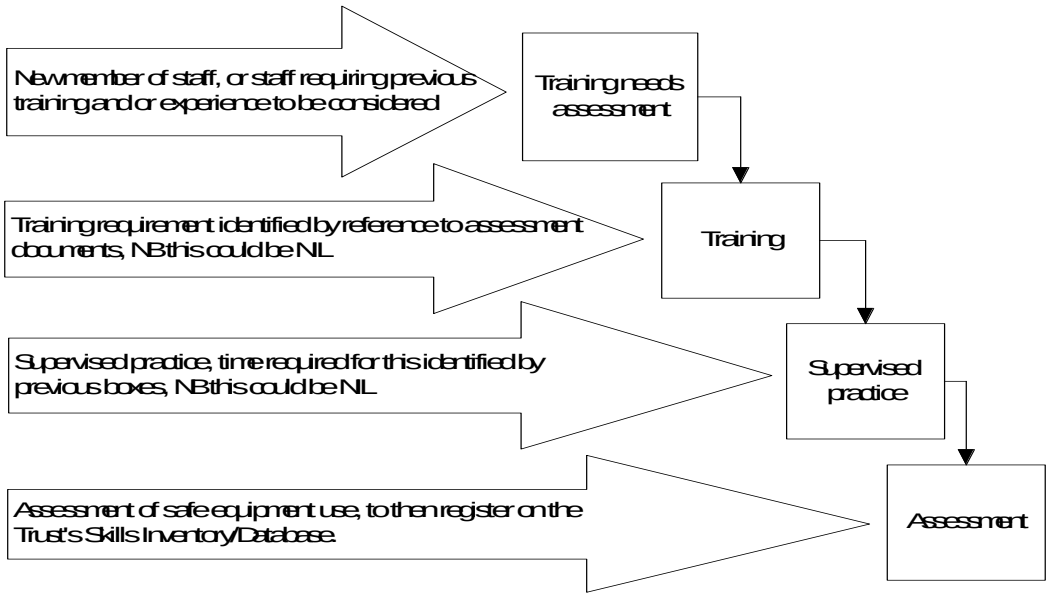
Breast Pump	2	1	2	L
Fluid Warming	1	1	1	L
Intermittent Pneumatic Compression Kit	2	1	2	L
Neurophys Devices	2	1	2	L
Non-diagnostic Ultrasound	1	1	1	L
Pneumatic Theatre Kit	2	1	2	L
Electronic Scales	1	2	2	L
Non-Path Microscopy	1	1	1	L
Endoscopes	1	3	3	L
Endoscope Cleaning Systems	1	3	3	L
Orthopaedic Equipment	1	2	2	L
Patient Trolleys	1	1	1	L
Patient Warming and Cooling	1	1	1	L
Pulp Product Macerator	1	1	1	L
Pressure Infuser	1	1	1	L
Scintillography	1	1	1	L
Deep Tissue Metal Detector	1	2	2	L
X-ray Equipment	1	2	2	L

Appendix 3 - How to use this form.

1. Identify the equipment you should be able to use with the Training Needs Analysis for your area. *(This is available on request and the Medical Devices Website)* e.g.

Device type. Please choose from drop down lists - click on input area then on Triangle, then choose the most relevent from the provided list.	**Risk Catagory** Automatically populated	Non-NVQ Trained Assistants (B2)	NVQ Trained assistant/practitioner (B3-4)	Reg Practitioner Junior (B5)	Reg Practitioner Senior (B6-7)	F1	F2	Specialist Rgeistrar	Consultant
Volumetric Pump - Baxter Colleagu	Extreme	X	X	Y	Y	X	X	X	X
12 lead ECG - MAC 1200 ECG	High	X	X	T	T	T	T	T	T
Patient Moving Equipment - Wheel	High	Y	Y	Y	Y	T	T	T	T
Patient Moving Equipment - Arjo Ma	High	Y	Y	Y	Y	X	X	X	X
Patient Moving Equipment - Arjo En	High	Y	Y	Y	Y	X	X	X	X

2. Follow the process below.



3. Consider the questions below with respect to the identified equipment. The training provided to you will allow you to answer the following.

   Am I confident

   - That I know what this piece of equipment is used for and what are its limitations?
   - I am not confusing this piece of equipment with another similar but inappropriate device?
   - I know if the equipment is safe and ready for use?
   - That I have all the materials needed for this task?
   - That I am aware of the common risks that occur in using this device, and that I can minimise these risks?
   - I can recognise if the equipment is operating normally, and would recognise a fault?
   - I know what to do when something goes wrong?
   - I know of the procedures to safely clean or decontaminate the device, and if they are needed?
   - I am aware of issues affecting the safe storage of the equipment after use?

4. Use the 'Competency Reporting Form Generator' available on flo to send these records

Verified assessment v2.3

NHS
University Hospitals of Derby and Burton
NHS Foundation Trust

Competency Record

For Derby Teaching Hospitals NHS Foundation Trust Employees,

Staff Details: (please print)

Directorate and Profession	
Department/Ward	
Name (as on payslip)	

Equipment that you use in your area

(See reverse for full instructions)

Name of equipment (Model and Make)	Training		Assessors Signature
	Required at this time? *(Y/N)*	Given? *(Date)*	*No signature = NOT Competent* *(Date)*

Verified assessment form

Appendix 4

Example Training Needs Analysis logo issue again

Please note layout of this form includes a date of completion and specific area identifiers

Medical Devices Training Needs Analysis TNA Derby Hospitals NHS Foundation Trust

This Training Needs Analysis tool is to assess the minimum competency requirements of all permanent staff

Minimum re-assessment times
Extreme = 3yrs
High = 5 yrs
Medium = 8yrs
Low = 10yrs

X	Not required for grade – Training not provided
T	Not essential to grade – Training can be provided for role development
Y	Essential to grade – Training must be provided

Ward/Department	
Agreed with	
Date completed	

Device type. Please choose from drop down lists - click on input area then on Triangle, then choose the most relevent from the provided list.	**Risk Catagory** Automatically populated	HCA's/Assistants (B2-3)	Trained Assistant (B4)	Reg Practtioner Junior (B5)	Reg Practtioner Senior (B6-7)	F1	F2	Specialist Rgeistrar	Consultant
Defibrillator - AED - FR2	Extreme	X	X	Y	Y	Y	Y	Y	T
Syringe Driver - Baxter GSP	Extreme	X	X	Y	Y	X	X	X	X
Syringe Driver - McKinley T34	Extreme	X	X	Y	Y	X	X	X	X
Syringe Driver - Omnifuse PCA	Extreme	X	X	Y	Y	X	X	X	X
Volumetric Pump - Baxter Colleague/Colleague 3	Extreme	X	X	Y	Y	X	X	X	X
Patient Moving Equipment - Wheel Chair (Standa	High	Y	Y	Y	Y	T	T	T	T
Patient Moving Equipment - Arjo Maxi Move	High	Y	Y	Y	Y	X	X	X	X
Patient Moving Equipment - Arjo Encore	High	Y	Y	Y	Y	X	X	X	X
Patient Moving Equipment - Bath Hoist (Gk Diana	High	T	T	T	T	X	X	X	X
Patient Moving Equipment - Ceiling Hoist (Guldm	High	Y	Y	Y	Y	X	X	X	X
Patient Moving Equipment - Rota Stand	High	Y	Y	Y	Y	X	X	X	X
12 lead ECG - MAC 1200 ECG	High	X	T	T	T	T	T	T	T
Flo-care Infinity	Medium	X	T	Y	Y	X	X	X	X
Abbott PCX - Near Patient Testing	Medium	Y	Y	Y	Y	X	X	X	X
Braun Proscan4000 Tympanic - Patient Observati	Medium	Y	Y	Y	Y	X	X	X	X
Datascope Series (Duo,Trio, V & Plus) - Patient C	Medium	Y	Y	Y	Y	T	T	T	T
Movement Sensor System (Falls) - Patient Observ	Medium	Y	Y	Y	Y	X	X	X	X
LSU Portable Suction - Suction - Electronic	Medium	X	T	Y	Y	T	T	T	T
Wall Suction - Suction - Gas	Medium	X	T	Y	Y	T	T	T	T
Vernacare 2020 - Bed Pan Macerator	Low	Y	Y	Y	Y	X	X	X	X
Autologic200 Mattress - Beds & Mattresses	Low	Y	Y	Y	Y	X	X	X	X
Enterprise 5000 Bed - Beds & Mattresses	Low	Y	Y	Y	Y	T	T	T	T
Pentaflex Foam Mattress - Beds & Mattresses	Low	Y	Y	Y	Y	X	X	X	X
Wall Flowmeters - Medical Gases and Flowmeters	Low	X	T	Y	Y	T	T	T	T
Pneumatic Theatre Kit - Intermittent Compression	Low	Y	Y	Y	Y	X	X	X	X
Scales - Electronic Scales	Low	Y	Y	Y	Y	X	X	X	X
Ultrasound - Fast Scan - Bladder Scanner BVI 30	Low	Y	Y	Y	Y	X	X	X	X

Details of all equipment are recorded centrally.

Appendix 5

Pathology Accreditation

OVERVIEW OF THE ACCREDITATION PROCESS

Accreditation is an on-going business process rather than a one-off achievement. Laboratories are assessed annually, confirming that they are continuing to operate according to strict standards. Derbyshire Pathology sits within the Trust and currently has 3 accreditation numbers RDH 9803, Chesterfield Royal Hospital (CRH) Blood Sciences 9807 and CRH Microbiology 9096.

The accreditation is against international standards (ISO 15189), Department of Health codes of practice, professional codes of conduct and best practice. References for all of these are available on the UKAS website [https://www.ukas.com].

The Pathology Accreditation process

For any laboratory seeking accreditation, United Kingdom Accreditation Service (UKAS) will carry out an assessment to ISO standard 15189 to establish that:

- The laboratory is impartial
- The laboratory is technically competent to do the work in question
- The resources and facilities are appropriate and sufficient for the work
- The laboratory's actual performance is to the required standard
- The laboratory is capable of sustaining the required level of performance.

The first step in seeking accreditation is for an applicant to assess themselves against the relevant ISO Standards 15189 (Medical Laboratory – Requirements for quality and competence) and then submit a completed application form to UKAS accompanied by a copy of the organisation's Quality Manual.

On receipt of the documentation the applicant is enrolled and UKAS assesses the application. If the application is not acceptable the department remains enrolled and UKAS assists the medical laboratory with progressing its application. If the application is acceptable arrangements are made for an assessment visit. This is carried out on site by a team consisting of an Assessment Manager and Peer assessors appointed by UKAS.

Following the on site assessment, a report is submitted to UKAS by the assessors. The report may recommend accreditation, identify conditions that must be met before accreditation is granted, or recommend that accreditation be refused and the applicant advised to reapply at a later date. The Assessment Manager will consider the recommendations and issue a decision. The final decision about accreditation status rests with UKAS.

Without UKAS accreditation the Laboratory would not be able to provide services.

Appendix 6

Medical Device Competency Reporting Process

Training Needs Analysis

- Use Ward / Department's Training needs Analysis (TNA) to ascertain which devices staff should be competent in. Different grades of staff will be able to use different devices. *(Available at request from Russel Turner or attached to evaluation document)*

Competency Standards

1. They know what this piece of equipment is used for and what its limitations are?
2. They are not confusing this piece of equipment with another similar but inappropriate device?
3. They know if the equipment is safe and ready for use?
4. They have all the materials needed for this task?
5. They are aware of the common risks that occur in using this device, and can minimise these risks?
6. They can recognise if the equipment is operating normally, and would recognise a fault?
7. They know what to do when something goes wrong?
8. They know of the procedures to safely clean or decontaminate the device, and if they are needed?
9. They are aware of issues affecting the safe storage of the equipment after use?

Assessment

- Verified Assessment to be done by Link Trainer or other competent staff

OR

- Quick sign off by Senior Sister to confirm staff are competent on listed devices

Reporting Competencies

- E-mail competencies to dhft.equipmentlibrary1@nhs.net via Competency Reporting Form Generator on Flo *(Preferable) this isn't correct as it isn't flo and is it still a dhft email address?*

OR

- E-mail quick sign off form to dhft.equipmentlibrary1@nhs.net

Inputting

- Competencies will be inputted onto Trust Central Database within 2 weeks of receipt
- Target Compliance for each department is >95%
- Compliance evaluations will be done at least every six months