Barnsley Hospital NHS
NHS Foundation Trust

POLICY CONTROL SHEET

(updated August 2011)

Policy Title and ID number:	**Medical Devices CCW2.7 and SE3.6**			
Sponsoring Director:	**Chief Nurse**			
Implementation Lead:	Deputy Chief Nurse			
Impact:	*(a) To patients*	**Yes**		
	(b) To Staff	**Yes**		
	(c) Financial	**Yes**		
	(d) Equality Impact Assessment (EIA)	Completed: **Yes**		
	(e) Counter Fraud assessed	Completed: **Yes / No**		
	(e) Other			
Training implications:	*To be incorporated into induction:* **Yes**			
Date of consultation:	***Approval Process***	**Date**	**Local Consultation**	**Date**
	Executive Team		*Joint Partnership Forum*	
	Board Committee:		*Local Negotiating Committee*	
	• *Clinical Governance*	*01/02/12*	*Infection Control Committee:*	
	• *Non Clinical Governance & Risk*		*Health & Safety Committee*	
	• *Audit Committee*		*Quality Safety Improvements & Effectiveness Board*	
	• *Finance Committee*			
	• *RATS*		*Investment Board*	
	Trust Board Approval / Ratification		*Patients Experience Board*	
	Other:		*Other:*	

Approval/Ratification at Trust Board:	*February 2012*	Version Number:	3
Date on Policy Warehouse:	*February 2012*	Team Brief Date:	
Circulation Date:		Date of next review:	January 2014

For completion by ET for *new* policies only:				
Additional Costs			Budget Code:	Revenue or Non Revenue
	(a) Training	£		
	(b) Implementation	£		
	(c) Capital	£		
	(d) Other	£		

Barnsley Hospital NHS
NHS Foundation Trust

MEDICAL DEVICE POLICY

POLICY ID: CCW 2.7 & SE 3.6

AUGUST 2007
(UPDATED SEPTEMBER 2009, JANUARY 2012)

SPONSORING DIRECTOR: CHIEF NURSE

MEDICAL DEVICE POLICY

(POLICY ID: CCW 2.7 & SE 3.6)

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POLICY

ABBREVIATIONS AND ACRONYMS

- CPR Cardiopulmonary Resuscitation
- NAO National Audit Office
- DoH Department of Health

MEDICAL DEVICE POLICY
(POLICY ID: CCW 2.7 & SE 3.6)

1. STATEMENT OF INTENT

The intent of the policy is to ensure the safety of all patients, staff, employees, contractors and volunteer workers, during the use of any medical equipment within the Trust. This will be done by:

- Maintaining effective organisational structures for equipment to ensure a Trust-wide consistent approach.
- Ensuring that appropriate systems are in place for identifying, assessing, and controlling equipment and safe systems of work within the Trust.
- Ensuring compliance with relevant NHS Litigation Authority (NHSLA) Risk Management Standards, Clinical Governance and Care Quality Commission standards and by promoting best practice.
- Ensuring that the Board of Directors and Chief Executive have assurance that appropriate systems are in place.

The procedures provide information for the necessary systems for safe, cost effective management of equipment.

No member of staff may use any medical equipment unless they have been trained and are competent in its safe use.

2. INTRODUCTION

Barnsley Hospital NHS Foundation Trust uses a diverse range of therapeutic, diagnostic, and technical support equipment in the provision of its services. It is the policy of the Trust that all equipment is used and maintained in the most safe and effective manner in line with NHSLA Risk Management Standards and Care Quality Commission standards.

A medical device is a health care product (including software), which, is defined by the Medical Devices Directive 93/42/EEC. This equipment is used for a patient in the investigation, diagnosis, treatment, prevention or alleviation of illness or injury.

The aims of the policy are to ensure that whenever equipment is used, it should be:

- suitable for its intended purpose
- properly understood by the user
- maintained in a safe and reasonable condition
- used only by staff who have been trained and deemed competent

The aims will be achieved through meeting the following core objectives:

- Ensuring Board level commitment to, and leadership of equipment management.

- Developing clinical effectiveness and governance frameworks to include the formal application of the equipment management process.
- Use of the medical equipment library
- Ensuring widespread employee participation and consultation in the purchase, rental, loan or trial; and the training, competent use, management and maintenance of equipment
- Providing a mechanism for all near misses and incidents involving equipment to be immediately reported, risk assessed and categorised by their potential consequences, and investigated to determine system failures, without assigning blame.
- Ensuring management systems are in place to provide safe practices, premises and equipment in the working environment. Systems of work must be designed to reduce the likelihood of human error occurring.
- Implementing robust systems of training and assurance of competence for all staff required to use or maintain equipment.
- Establishing a risk management process that is applied to contract management especially when acquiring, expanding or outsourcing services, equipment or facilities. Contracts must be reviewed and written to ensure that only reasonable risks are accepted.
- On all Trust premises, whether owned or shared, putting safe systems of work in place to protect patients, visitors and staff.
- Providing realistic resources to implement and support the strategy and policy.
- Providing an inventory of medical equipment
- Providing a clear process to identify which permanent staff are authorised to use equipment
- Providing a clear process to determine what training is required to use equipment identified on the inventory and the frequency of updates to training
- Have a process to identify training needs of staff and ensure that these are met
- Have a clear risk assessment process to support the need for planned periodic maintenance
- Have a clear process for ensuring that medical devices are maintained
- Have a clear process to ensure that equipment is repaired

3. IMPLEMENTATION

No member of staff may use any equipment unless they have been trained and are competent in its safe use.

The Trust operates a range of training provision designed to assist clinical staff with the safe use of equipment in the workplace. New equipment or new medical or clinical techniques must not be introduced to the Trust without the proper approval of the equipment, training and competency expectations.

Corporate Induction
The role of the Learning & Development Department in liaison with Departmental Managers is to co-ordinate corporate induction for all staff, identify training needs via staff appraisal procedures, including KSF outlines and ensure relevant training programmes are established and accessed.

Staff who are required to have patient contact will have access to the corporate induction and in line with the corporate curriculum:

- Clinical Risk Training
- CPR training and related equipment
- Health & Safety Awareness
- Moving and Handling training and related equipment
- Infection Control training

Departmental Induction/Orientation
On induction into their department all staff will receive a local induction to include formal teaching and systematic assessment of competence for all equipment that may be encountered on that department that they may be required to use. Certain hospital departments provide specialist services and training will include any legislative requirements e.g. Medical Imaging, Medical Physics and Pathology Laboratories.

Individual wards and departments will hold information relating to medical equipment used in that area, which staff groups should receive training for the medical equipment used within that area and how often that training should be updated. However, staff are expected to ask for update training at any time if they feel uncertain regarding any aspect of equipment use.

Standards of Training and Record Keeping
Training provision and record keeping is becoming an increasingly important aspect of demonstrating staff competency and meeting legal or qualitative standards in patient care. A systematic framework will be adopted with any programme of training to include:

- A programme of training recognised and approved by the Trust
- Training provided by staff who are approved by the Trust as competent in the use of the equipment and who have a teaching and assessment qualification.
- A comprehensive framework of competency assessment and supervision within an agreed criteria
- Systems for maintaining competence and periodic audit
- A record of staff training kept on each ward/department.

Staff not achieving competency levels will require retraining and a period of supervised practice.

Training in the safe use of equipment will include:

- Safety checks to be completed prior to using the equipment
- Safe use of the equipment including alarms
- Other devices required for use with the equipment
- Familiarity with and location of the user manual
- Hazards and risks associated with using the equipment

- Decontamination/cleaning procedure
- Reporting faults
- Maintenance schedule

Ward/department equipment controllers will be responsible for completing training records for each type of equipment in use in their particular ward or department. Each member of staff who has been trained will sign the training records to verify that they have been trained and fully understand all the information they have been given.

4. MANAGEMENT ARRANGEMENTS

Overall responsibility for the management of risk lies with the Chief Executive as Accountable Officer.

All Trust Directors are responsible, collectively, for the Trust's systems of internal control and management. The Board of Directors needs to be satisfied that appropriate policies and procedures are in place and that systems are functioning effectively. The Board of Directors has delegated its accountability arrangements for medical equipment management to the Chief Nurse.

The responsibility for the management of equipment necessarily involves the whole management chain of command, and all members of staff have a responsibility to ensure the effectiveness of the equipment management system.

Within that system there are certain key officers and specific functions are outlined below:

<u>Chief Nurse</u>

- To ensure that policy and procedures are agreed through consultation with relevant staff groups
- To ensure that the overarching policy is updated regularly in line with national guidance and audit reports
- To keep the Chief Executive and Board of Directors up to date with progress and highlight any areas of concern

<u>Divisional Directors/Deputy Divisional Directors/Assistant Directors of Nursing/Managers/Heads of Departments</u>

- To ensure Medical Device Co-ordinators and Equipment Controllers are in place for all work areas as appropriate
- To ensure risk assessments are completed within their area of responsibility and reported to the clinical risk leads accordingly
- To ensure that following risk assessments, safe systems of work are introduced to minimise risks to staff and patients,
- To ensure that staff are trained to use the equipment appropriate to their area of work to the correct level of competence
- To ensure that sufficient staff are trained to carry out appropriate clinical and non-clinical risk assessments dependent on the needs for the area concerned.
- To ensure that adequate resources are available within the work area to follow correct procedures

- To ensure that regular audit of agreed processes and procedures takes place to monitor the effectiveness of practice and that remedial action is implemented where required

Corporate Medical Device Co-ordinator

The Corporate Medical Device Co-ordinator is a key post as part of the overall management and safe working practice regarding medical devices. It has been agreed that this function will be undertaken by the Deputy Chief Nurse. The post holder will:

- Act as a central lead for the Medical Device Co-ordinators
- Meet regularly with Medical Device Co-ordinators to ensure momentum of the work
- Give support to Medical Device Co-ordinators when required
- Ensure a record of all departmental Equipment Controllers is maintained for the Trust
- Effectively communicate between Medical Device Co-ordinators and Medical & Surgical Equipment Committee
- Act as a lead to ensure NHSLA and Care Quality Commission standards are implemented
- Ensure procedures are available to guide practice
- Ensure training programmes and competency assurance for staff in the safe use of medical devices are in place
- Liaise with other key staff throughout the organisation when required to ensure standards are met
- Ensure a programme of audit and evaluation is undertaken

Medical Engineering Manager

HE198 recommends that each Trust appoint a Manager of Technical Servicing to be responsible for the overall technical management of equipment maintenance. Within the Trust these duties are undertaken by the Medical Engineering Manager.

The duties include the following:

- Receipt and commissioning of equipment
- Provision of expert advice on servicing, repair and modification of equipment, the suitability of contractors, the capability of in-house facilities and the technical content of maintenance contracts
- Supervision of scheduled servicing whether carried out by in-house or contractor staff
- Responsibility for the in-house servicing team including control of technical training to acquire and maintain the necessary degree of expertise
- Keep an up to date inventory of re-usable medical devices and equipment used throughout the Trust
- Ensure that a process is in place to facilitate the appropriate maintenance and repair of re-usable medical devices and equipment
- Ensure that a process is in place to ensure that calibration is checked within specified timeframes for re-usable medical devices
- Maintenance of service records to produce a history of equipment for its lifetime and retention of records for as long as required by the Consumer Protection Act (1987) and Health Service Guidance 99/053
- Ensuring that the interests of the user and patient are protected specifically with respect to the Health and Safety at work Act (1974)

Central Alerting System (CAS) Liaison Officer

The Liaison Officer for the Trust is the Clinical Risk Advisor.

The main responsibilities for the Liaison Officer are as follows:

- Act as the contact point for Medicines and Healthcare Products Regulatory Agency (MHRA) CAS alerts
- Ensure that procedures are in place for the reporting of adverse incidents involving medical equipment to the MHRA
- Act as the point of receipt for MHRA alert publications
- Ensure dissemination of CAS alert publications to relevant personnel within the Trust
- Collate responses and report back to MHRA regarding alerts

Infection Control Team

The Infection Control Team will advise on all infection risks associated with equipment including:

- Maintenance of infection control procedures
- Advice on purchase
- Approval of decontamination systems

Supplies Manager

The Supplies Manager must ensure the integrity of the procurement process by:

- Ensuring procedures for equipment procurement are carried out in accordance with MHRA and NAO recommendations
- Ensuring all risks associated with the procurement of any equipment is minimised
- Ensuring that equipment trials, loans free issues and donated items are supported by appropriate indemnity arrangements
- Ensuring that all purchased devices are CE marked

Medical Device Co-ordinators Committee

The committee will be responsible for:

- Ensuring that the Medical Devices work remains focused and progresses at ward/department level.
- Sharing information and ensuring a corporate approach to use, maintenance and training for medical devices
- Providing a forum for sharing best practice
- Providing advice and support to Equipment Controllers
- Acting as a conduit for information from and to the Medical & Surgical Equipment and Supplies Committee and clinical areas
- Monitoring adherence to agreed processes and procedures
- Ensuring that policy and procedures reflect national requirements/guidance
- Ensuring that competency statements are available for medical equipment used throughout the Trust

Medical & Surgical Equipment and Supplies Committee

The Trust wide Medical and Surgical Committee has been established in order to:

- Approve the purchase of medical, laboratory, radiology and theatre equipment and instrumentation, that falls within the definition of capital purchases.

- Decide on medical equipment priorities in order to support patient care
- To approve an equipment standardisation programme to improve safety and cost effectiveness as recommended by the Medical equipment Standardisation Group
- Recommend the replacement of medical equipment
- Produce a medical equipment strategy, which identifies the timely replacement of all major items of equipment
- Consider clinical governance issues related to medical equipment and form key linkages with the governance group
- Produce an annual procurement report for submission to the Investment Board

Divisional Medical Device Co-ordinators

The Divisional Medical Device Co-ordinators will be responsible for monitoring the implementation of medical device standards into practice and acting as liaison between the Medical Device Co-ordinator Group and the clinical areas. The Divisional Medical Device Co-ordinator will: -

- Perform the duties of this role for a Division or specialist area
- Provide advice for the Equipment Controllers in their area
- Ensure the agreed standards are being implemented in their area
- Disseminate the information between the Medical Device Co-ordinator meeting and the Equipment Controllers
- Participate in medical device audit arrangements

Ward/department Equipment Controllers

Equipment Controllers are ward/department based staff who co-ordinate activities related to medical devices in their clinical area. The Equipment Controller will: -

- Maintain an equipment profile of ward/department equipment
- Maintain a library of operator instructions
- Liaise with the medical engineering department to update the Trust asset register (Trust equipment profile)
- Act as the key contact for communication with medical engineering and maintenance
- Ensure that on induction to an area all new members of staff receive training on how to report incidents relating to medical devices
- Ensure that all members of staff in their area receive appropriate training regarding medical equipment
- Maintain an up to date record of staff training
- Ensure that a member of staff who has knowledge in relation to the specific medical device accepts equipment into service
- Verify that servicing arrangements reflect the interests of users and provide safe equipment for patients and staff
- Examine equipment records to ensure that repairs and servicing have been carried out as scheduled
- Ensure that formal arrangements for the handing over of equipment for repair, servicing and receiving it back when the work has been completed, are followed
- Ensure that the ward/department has access to the Trust decontamination procedure and that this is followed
- Ensure that equipment is stored as per manufacturers recommendations when not in use

- Keep MHRA notices/device bulletins up to date and actioned as appropriate
- Participate in medical device audit arrangements

The names of the Divisional Medical Device Co-ordinators and Equipment Controllers must be known to all responsible for the management of equipment. An up-to-date register of all names will be kept in the ward/department held medical device files.

Radiation Protection Advisor

The Trust has an appointed Radiation Protection Advisor (RPA) and Radiation Protection Supervisors (RPS) as a requirement of The Ionising Radiation Regulations 1999 (IRR (99)).

Responsibilities of these staff include:

- Undertaking risk assessments on all new equipment as part of the evaluation process to ensure that radiation doses are as low as practicable
- Maintenance of an accurate equipment profile
- Implementation and monitoring of an effective Quality Assurance Programme
- Ensure that suitable maintenance provision is made
- Ensuring annual Medical Physics checks are undertaken
- Investigating and reporting of adverse incidents to either the DoH or MHRA as appropriate dependant upon the nature and severity of the incident

Documentation to ensure compliance with IRR (99) is maintained by the RPS and is available for inspection.

Staff

Responsibilities include:

- Access appropriate training
- Report any untoward incidents or near misses
- Remove and label unsafe equipment from service appropriately
- Report any hazardous or dangerous work situation to management and complete Sentinel incident reports accordingly
- Use equipment strictly in accordance with any training provided and equipment guidance and comply with the safe system of work
- Assist where required with audit processes

5. AUDIT AND EVALUATION

Audit of processes and procedures will take place, co-ordinated via the Deputy Chief Nurse, and will be reported to the Medical and Surgical Equipment Committee (at least once annually). This will be facilitated by use of audits as outlined in the annual medical device work plan, including decontamination of equipment, competency assessment documentation and staff knowledge regarding the use of individual pieces of equipment.

Any incidents will be reported via the Sentinel incident reporting system. Any serious incidents (SIs) will be reported through the Strategic Risk Group to the Quality and Safety Improvement and Effectiveness Board and to the PCT. Any relevant incidents will be reported to the MHRA. Shared learning and Trust wide action plans will be developed from any SIs as required.

6. REVIEW DATE

September 2013

7. BIBLIOGRAPHY

- Health and Safety at Work etc Act 1974
- Consumer Protection Act 1987
- Health Equipment Information 1988 (November 1990)
- Electricity at Work Regulations 1989
- Provision and Use of Work Equipment Regulations 1998
- Managing Medical Devices DB2006(05) MHRA
- The Management of Medical Equipment in NHS Acute Trusts in England. National Audit Office. June 1999.
- HSC 1999/179 – Controls assurance in infection control: decontamination of medical devices
- Medical Devices and Equipment Management: Repair and Maintenance Provision – Medical Devices Agency MDA DB2000(02)
- Equipped to Care: The Safe Use of Medical Devices in the 21st Century – Medical Devices Agency (April 2000)
- Reporting adverse incidents and disseminating Medical Devices Alerts - Safety Notice MDA/2004/001
- NHSLA Risk Management Standards for Acute trusts, Primary Care Trusts and Independent sector Providers of NHS Care 2009/10
- Healthcare Commission Standards for Better Health, Inspection Guide 2007/2008
- Care Quality Commission Criteria for Assessing Core Standards in 2009/10 : Acute Trusts

CROSS REFERENCE DOCUMENTS/ PROCEDURES

- Decontamination policy
- Incident reporting policy
- Medical device co-ordinator and equipment controller guidelines
- Operational document on the procurement of medical devices
- Operational document on the repair and maintenance provision for medical devices
- Operational procedures for the sale, transfer of ownership, condemning and disposal of used medical devices
- Operational procedures of the medical equipment library
- Policy for the introduction of new clinical procedures
- Policy on the manufacture and modification of medical devices
- Operational procedures of the Trust medical equipment standardisation group
- Procedure for the acceptance testing of newly delivered medical devices
- Procedure for medical device prescribing
- Procedure for patients' being end users of medical devices
- Procedure for tracking moveable equipment
- Procedure for tracking manufacturer's instructions as revised copies are issued
- Medical Device Training
- Single use medical devices
- Risk assessment procedure for planned preventive maintenance of reusable medical devices
- Service Level Agreement for repair of re-useable medical devices