CLINICAL POLICY

MEDICAL DEVICES POLICY

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Approved by (committee, group, manager)	Mobile Electrical Medical Equipment (MEME) Group
Approving signature	Minutes of meeting received
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Version History:

Date	Version	Author name and designation	Summary of main changes
September 2003	1.0	Helen Porter – Director of Nursing & Clinical Governance	
November 2007	2.0	Kate Smith – Head of Clinical Governance	
October 2009	3.0	Kate Smith – Head of Clinical Governance	
July 2010	4.0	Natalie Atkinson – Medical Devices Co-ordinator	Transfer to new template – full policy review
July 2011	4.1	Natalie Atkinson – Medical Devices Co-Ordinator	Update of Processes
January 2012	5.0	Natalie Atkinson – Medical Devices Co-ordinator	Update of processes
February 2015	5.1	Tony Marsland – Medical Devices Co-Ordinator	Update of Processes
February 2016	6.0	Tony Marsland – Medical Devices Co-ordinator	Update of processes
April 2017	7.0	Tony Marsland – Medical Devices Co-ordinator	
January 2018	8.0	Tony Marsland – Medical Devices & Commodities Manager	Changes to job titles,
February 2019	9.0	Tony Marsland – Medical Devices & Commodities Manager	Update of processes, Caveat in 3.0 Scope relating to Haematology Directorate. Changes to wording to reflect implementation of 3rd party contract for EBME provision
February 2020	10.0	Tony Marsland – Medical Devices & Commodities Manager	Change to approving committee, review to update practise changes during 2019, Review for fit for purpose at CCC-L. 3.0 Scope remains as is until full relocation of Haematology until September 2020. Review period changed to 3 yearly.

Table of Contents

1.0 Introduction

The policy includes guidance for the:

- Purchase
- Acceptance
- Decontamination
- Maintenance
- Repair
- Monitoring and replacement of devices
- Training of users (see policy Training Requirements to Operate Medical Equipment)

2.0 Purpose

- To ensure that whenever a medical device is used, it should be:
  - Suitable for its intended purpose
  - Properly understood by the professional user (e.g. health care professional)
  - Maintained in a safe and reliable condition.
  - Condemned and disposed of according to manufacturer's instructions and appropriate legislation.
- Ensure that there are systems in place to minimise all risks associated with acquisition, use and decommissioning of all medical devices or equipment used at CCC.
- To provide a structure that establishes the roles and responsibilities of staff.
- To provide guidance on compliance with statutory and NHS requirements.
- To inform and educate staff in the use and care of medical devices.
- To reduce the risk of any medical device from being prescribed incorrectly, or from the device failing and causing injury to patients or staff.
- To ensure that suitable and sufficient assessments of the risk are in place.
- To ensure that there is training appropriate to the users' requirements and for technical staff in the use and maintenance of medical devices.
- To ensure that purchases of medical devices are funded including installation, training, maintenance and revenue costs.

3.0 Scope

This Policy relates to the MHRA document DB2006 (5) “Managing Medical Devices Guidance for Healthcare and Social Services Organisations” and applies to all equipment used within CCC.

Adoption of the Royal Liverpool NHS Trust Policies: The Clatterbridge Cancer Centre Haemato-oncology service is located within the Royal Liverpool NHS Trust. The service will continue to adopt Royal Liverpool Hospital policy / procedure / protocol (Medical Devices) which is currently under review.

4.0 Responsibilities

All NHS organisations are subject to legal and statutory requirements relating to ‘the duty of care’ that require employers to provide competent and safe fellow employees, safe equipment and places of work, and safe systems of work.

4.1 Board Level Lead

The Board level Lead for Medical Devices is the **Director of Nursing and Quality.** He/she reports to the Trust Executive Group and the Board. This post is supported by the **Medical Devices & Commodities Manager (MDCM)**.

4.2 The Trust Mobile Electrical Medical Equipment (MEME) Group

This Group is responsible for ensuring that a common Trust-wide approach is taken to issues of equipment management. MEME consists of a multi-disciplinary team of staff from across the Trust dealing with management of capital and revenue, specialist or departmental equipment. In particular, this group is responsible for:

- Ensuring that risks are appropriately considered:
  - Receiving risk assessments, informing the Risk Management Committee and ensuring that entries are made to the Risk Register.
  - Linking with the Health and Safety Committee and its specialist advisers on:
    - Infection Control
    - Radiation
    - COSHH

- General H&S

- Ensuring that equipment plans are complete for:
  - Procurement and installation of equipment, including technical specification and tendering arrangements.
  - Acceptance and commissioning of equipment, including any critical examinations as may be necessary.
  - Ongoing management of quality and performance, including maintenance and quality assurance programmes.
  - Clinical operation of the equipment, including operational procedures and training requirements.
  - Contingency arrangements, including decontamination guidelines, disaster recovery.
- Ensuring financial planning:
  - Provision of appropriate capital and revenue budgets
  - Depreciation and replacement planning

The MEME ensures that the requirements of the Trust for the acquisition, maintenance and management of medical devices/equipment are identified and delivered. It will ensure appropriate governance procedures are adhered to in relation to staff training and competencies

(NB for the purpose of this group “medical devices/equipment” includes all medical devices, consumables and peripherals)

The MEME consists of representatives from each of the Trusts departments with medical device responsibility (see Appendix 1 for membership and Terms of Reference). MEME will be responsible for the initiation of specific project groups to give assurances for above.

4.3 Medical Devices & Commodities Manager (MDCM)

The MDCM is responsible for ensuring that systems are in place for the management of medical equipment and its use. This involves delegating as appropriate to key sub-groups, specific responsibilities for specialist equipment.

4.4 Equipment Project Groups

These Groups report to the MEME on specific departmental issues or on specialist equipment issues. The size and membership of these project groups is determined at departmental level according to the equipment issues. These project groups will be responsible for providing information to the MDCo on the issues identified above, so that the MEME can carry out its specific responsibilities. Where complex specialist equipment is being considered which requires individual and specific project management arrangements, then the relevant Equipment Project group will:

- Act as the **Project Management Team** and develop the **Project Management Plan**
- Appoint members to a **Project Group** to carry out the Project Management Plan.

The Project Management Plan will include the development of individual business cases as necessary and will keep the MEME advised of progress as a matter of course.

The project group will take advice from expert advisors as necessary, and will include members of the various departments involved (including those providing services within CCC such as The Electrical and Biomedical Engineering Department [EBME], Technical Services and the MDCM) as appropriate. The project group will develop an inventory of medical devices, documentation and training to populate the Trust-wide database, and will provide information on risk assessments. The Project group will, as part of their deliberations on risk, consider the pros and cons of standardising on specific equipment models. The Project group will, for equipment which falls within their remit, ensure that equipment replacement and development plans are in place. The Project group will establish procedures for introduction of service developments based upon medical devices. A member of each Project group will act on the Trust wide MEME and will form the official link between the Project group and the MEME.

4.5 The Risk Management Facilitator

Acts as the Liaison Officer and is responsible for the Coordination of effective reporting of adverse incidents involving medical devices and the dissemination of advice and recommendations issued by the MHRA.

4.6 Heads of Department

The Heads of Department are responsible for ensuring staff training in relation to the safe use of medical devices and equipment and for keeping a record of this training locally. Heads of Department are responsible for ensuring medical devices and equipment are maintained in a safe and reliable condition and for reporting any device or equipment which fails this standard and removing it immediately from service as appropriate. Heads of Department must report any incident through the Trust wide incident reporting mechanism relating to medical devices.

4.6.1 Departmental Medical Device Leads

Each department responsible for a medical device has a nominated Medical Device Lead. This person will be responsible for the efficacy of service schedules relating to that equipment and will report any exceptions to the Head of Department and MDCo. The nominated medical device lead will attend the scheduled MDCo and provide a regular report on departmental activity.

The monthly report will provide the following:

- Prospective additions to department equipment
- Equipment on trial
- Equipment ordered
- Equipment received
- Equipment training carried out
- Equipment out of service
- Equipment condemned
- Any issues concerning the operation or use of equipment

4.7 Staff

Individual members of staff are responsible for ensuring they are properly trained in the use of medical devices/equipment and for attending updates as required and provided by the Trust, also for reporting equipment which fails to be in a safe and reliable condition and for removing it from service as appropriate. Staff must report any incident through the Trust wide incident reporting mechanism.

4.8 EBME 3rd Party Provider

Will report monthly to the MEME in the following manner:

- All items repaired that month
- Any items located which are overdue service
- Any items located where servicing completed (also items requiring calibration)
- All new items added to the database
- All items de-commissioned or withdrawn from service

5.0 Laws & Regulation

Please see Section 3.0 above

6.0 Definitions

The term ‘medical device’ covers a broad range of products including those used every day in most health care settings and can be defined as any instrument, apparatus, appliance, material or healthcare product, excluding drugs, used for a patient or client for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of a disease;
- Diagnosis, monitoring, treatment, or alleviation of, or compensation for, an injury or handicap;
- Investigation, replacement or modification of the anatomy or of a physiological process;
- Control of conception.

For the purpose of this standard, the term ‘medical device’ at CCC should be taken to include:

- Active implantable medical devices
- In–vitro diagnostic medical devices

A more extensive list of products which fall within the definition of medical device is provided on the MHRA (medicines and health care products regulatory agency) website at: **www.mhra.gov.uk**

7.0 Main Body of Policy

7.1 Purchasing

The MEME will ensure that the process for specifying purchases, commissioning, training staff, maintenance and disposal are in place. Standing Orders, Standing Financial Instructions and other corporate instruments must be complied with. EBME are to maintain asset databases for all medical devices that fall within its jurisdiction.

All staff operating or maintaining medical devices must have highlighted their need and received training suitable to their needs, and have access to a comprehensive user guide.

The selection process includes consideration of all issues that relate to its use and is governed by the MEME. An Equipment Assessment Form (see Appendix 2) must be completed by the requisitioner and presented to the MEME. Where an Item of equipment is new to the Trust it is required, where possible, to be trialed for suitability. A Trial Assessment Form (see Appendix 3) will be completed by both the Trust Health and Safety Officer and Infection Control staff as a minimum and by all other parties for whom the equipment is intended.

7.2 Incident Reporting

Any adverse incidents involving medical devices are to be reported using the Trust incident reporting process; these will be passed to the Risk Management Facilitator who will take appropriate action:-

- See Incident reporting Policy.
- The Risk Management Facilitator has the responsibility for the reporting of device related adverse incidents to MHRA as detailed in DB2006(05)
- Devices involved in an adverse incident together with other material evidence (e.g. packaging of a single use device) should be clearly identified, until MHRA's device specialists have been consulted. The state of the device(s) at the time of the incident should be recorded for use in any subsequent investigation.
- Local action is taken as necessary to ensure the safety of patients, users and others.

- All staff, including contractors, at all levels are aware of their responsibilities and of the procedures to be used to report adverse incidents and isolate and retain defective items.
- The Risk Management Facilitator is responsible for recording and reporting incidents in order to ensure that adverse incidents occurring within the organisation are not repeated.
- A bi-monthly report received from the Risk Management facilitator will be submitted to the MDCo by the MDCM to advise on all incidents relating to Medical Devices.

7.3 Development, modifications and trials

Devices produced within the CCC, as a matter of good practice, are manufactured in accordance with the Medical Devices Regulations. Adequate documentation should be produced for all in-house manufacturing activities. Modifying existing devices, or using them for purposes not intended by the manufacturer may have safety implications and will almost certainly transfer liability to the user organisation. Where devices are subject to 'full refurbishment' by a healthcare organisation, the organisation may need to comply with the Medical Devices Regulations.

Note: Full guidance on the implications of the **Medicines & Healthcare products Regulatory Agency (**MHRA) Regulations on healthcare and other related establishments has been published by the MHRA.

Specific pieces of equipment will be subject to specific legislation (e.g. Ionising Radiations Regulations and Ionising Radiations (Medical exposures & regulations) and risk assessments. Any specific regulations will need to be addressed by the MEME.

Where a piece of equipment is new to the Trust, and where possible, a trial will be carried out to ensure fitness for purpose. An Equipment Trial Assessment Form will be completed and submitted to the MEME (see Appendix 2).

7.4 Safe use of Equipment

The manufacturer is responsible for supplying appropriate instructions including information needed to use the device safely (taking account of the training and

knowledge of potential users), the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times, and any special storage and handling conditions.

Providers of devices for end-users must pass on the manufacturer's instructions about safe use of the product to minimise any legal liability in the case of an accident. These may be supplemented by the organisations own operational procedures. Records must be kept of instructions, whether written or verbal, where given to end-users in respect of certain equipment.

End users must have received instructions and be aware of their importance. Training records must comply with other requirements such as IR(ME)R and Training requirements policy.

The MDCM works with Key trainers, HR departments and Departmental Heads to develop, manage and maintain appropriate electronic training records and progress reports to be submitted as a standing agenda item to the MDCo.

7.5 Manufacturer's information

Copies of all instructions are to be forwarded to relevant individuals, e.g. Head of Physics, Head of Technical Services, MDCM and EBME, who will have responsibility for the holding of and dissemination of those instructions. Also to ensure that a system is in place for keeping track of all the sets of instructions for equipment under their remit, and for replacing them with the revised versions when necessary.

7.6 User Instructions

Instructions for use should be suitable for end-users. Where the end-user is identified as a current or former patient or carer, instructions for use should be suitable for the end-user. These should be agreed by the Patient and Public Involvement Group. Where end-users have particular problems such as disabilities or medical conditions, a clinical assessment of suitability will be undertaken. Additional information may need to be given and, in some instances (e.g. where people are blind or confused), special training will need to be given. The person providing the equipment is responsible for this assessment.

It may also be necessary to write instructions locally if devices are linked to serve a novel function. In such circumstances, it is important to write instructions which are adequate. A topic checklist is given as follows for consideration:

- Placement - should instructions be printed on the device itself, or its immediate packaging, or supplied as a leaflet?
- Content - instructions must be precise and clear, and should include commonsense advice.
- Print size - users may have visual impairment.
- Technical or difficult language - users may lack technical knowledge. Instructions may be incomprehensible.
- Translation from foreign language - may not be accurate.
- Translation into other languages - end-users must understand the instructions.

In some situations end-users need a telephone advice line as well as written instructions. The Head of Department/Manager will identify where this is a requirement.

7.7 Acceptance of equipment

The purchaser will ensure notification is made to the MEME of the delivery and all associated actions stemming from it.

All equipment that is delivered as new to CCC must have an accompanying completed Equipment Assessment Form (see Appendix 2).

This will include areas such as (but not exhaustive):

- Functional check, does it meet specification?
- Any damage when delivered
- Safety check.
- Calibration and measurement.
- PAT testing

This will be carried out mainly by staff from CCC Physics, Technical Services Department and EBME working in association with the department in which the

equipment is located. Some or all of this work will be covered by the quality control system registered to ISO2002 standard.

Checks may also be made by external agencies according to the equipment procured e.g. diagnostic imaging equipment. New equipment is **not** authorised for use prior to the above checks being made.

When a device is first put into service, records will need updating, staff may require new/refresher training and planned preventative maintenance (where required) will be put in place by the Head of Department and advised to the MDCo. Professional users should be aware when they are the first person to use a new device.

- Record keeping – As part of the acceptance check the item will be allocated a unique asset number via EBME, Technical Services or MDCM, and will be entered into an inventory; this will be clearly visible via a label with local serial/control number attached.
- Training - appropriate training schedule (where required) for users will be organised prior to delivery by the Department Head:

- for new models of a familiar device, professional users need to have access to any revisions to the operator's manual, how any controls and adjustments work, and to be aware of potential errors arising from misleading similarities to existing devices;
- for complex or novel devices, formal training sessions, preferably run by the manufacturer, alternatively by an appropriately trained professional, will be required;
- Any necessary training for technical and maintenance staff will be organised by the EBME/Technical Services Department as required; and respective training records will be updated.

- Planned preventative maintenance –day-to-day checks and operations will be derived, agreed and documented. The servicing organisation to be used will be identified and a service plan developed in accordance with the manufacturer’s recommendations. The record keeping system will be updated; maintenance manuals will be filed and documented.
- Labels and documentation - corporate labels, where appropriate, will be attached to the equipment, in addition, for the end-user it is recommended:

- warning professional users that this is a new device and they should monitor its introduction;
- warning end-users to wait until they have been trained before starting to use;
- giving date when preventative maintenance will be needed; or
- Giving basic instructions for use.

- Copies of manuals will be supplied / easily accessible to users of the device.
- For large items (e.g. sterilising plant, x-ray, laboratory analysers) a record will be opened, to remain with the device), detailing acceptance test results and appropriate contact details in case of problems.

7.8 Loan / Trial Equipment

Procedures for the delivery of loaned or equipment being trialed should pay attention to safety issues in terms, for example, of avoidance of cross-infection, delivery of the correct item, and commissioning. A system for identifying equipment in terms of whether it is simple requires assembly, requires fixing, requires that a prescribing professional be present, requires special instructions for the end-user- and so indicate the time and personnel needed to ensure successful and safe delivery, installation and end user training will be developed.

Acceptance of loan or trial equipment must be notified to the MEME and (where appropriate) be subject to a number of the same processes as new equipment. Its loan period must be clearly identified and its application clearly specified. Where the loan item is expected to be long term, clear areas of responsibility to it must be documented i.e. servicing, repair, calibration or specialist treatment (to include decontamination) and storage. Should a fault occur with loan equipment and a replacement sought these processes need to be repeated in full.

For use of bariatric equipment please refer to CCC Moving & Handling policy.

7.9 Storage

Inappropriate storage of items affects their subsequent safe use. Manufacturer's information and instructions both on storage conditions and shelf life should be followed:

- Physical conditions – ensuring appropriate physical conditions for storage avoiding dirty or wet conditions, inappropriate temperate or humidity (labels on packaging should indicate appropriate storage conditions and should also be covered within operator manuals). This will include new or refurbished buildings for equipment such as Linear Accelerators.
- Storage system – ensuring appropriate storage racking, avoiding stacks too high, or storing fragile equipment too far off the ground which could likely cause damage by falling from shelves. Storage should also take into consideration shelf life and stock rotation.
- Ensuring separation of equipment needing decontamination and repair from equipment ready to issue – adequacy of space for demarcated areas for quarantine etc; adequacy of labeling of zones, packaging and labeling of equipment.

7.10 Single Use / Single Patient Use Devices

Single Use equipment carries the symbol  and is intended to be used only once on a single patient. A period of safe use will be specified by the manufacturers or by local policies. It may not be possible to safely reuse such equipment due to durability or decontamination limitations. Therefore anything carrying the 'Single Use' symbol must not be reprocessed or reused.

Single Patient Use equipment is only intended to be used on a single patient and then disposed of. Such equipment may be used repeatedly on the same patient if adequate decontamination is undertaken between uses but it is not possible to use safely on other patients. The manufacturer's guidance on decontamination processes must be followed.

Appropriate methods of disposal must also be identified.

7.11 Prescribing

The prescription of equipment is the responsibility of the prescribing professionals. Prescription of different types of equipment is undertaken only by suitably qualified and experienced staff. Patients prescribed any such equipment will be fully trained in its use.

7.12 Systematic Inventory

All reusable medical devices and equipment are to be recorded on a Trust wide inventory. A record of the stock of devices currently available for use is available and managed by the MDCM / EBME, in addition to records by the users. In some areas, this is a specific requirement of IRMER (e.g. records of equipment, maintenance and training). The record database provides an inventory, service histories and technical details. Information available includes: the registered location of a given item; its – manufacturer, supplier and purchase date along with its service history. It records how many items are available for use (or loan); how many are undergoing repair or servicing and records condemned items and the rationale for such.

7.13 Maintenance and repair

Day to day maintenance & calibration:

Process for ensuring that all reusable medical devices and equipment are properly maintained and repaired:

7.13.1 Management of Radiotherapy Planning & Treatment equipment

Therapy beam and simulation equipment is managed in accordance with the Quality Assurance System in Radiotherapy (QART) which complies with the ISO9001: 2008 Quality Standard. All megavoltage equipment and simulators are subject to daily dose checks before use. Full quality control checks are grouped as monthly, 3-monthly, 6-monthly and annual. Kilovoltage equipment is subject to daily dose checks and full Quality Control checks are carried out every 4 weeks. Pre-treatment scanners are subject to daily and weekly Quality Control checks. Routine maintenance is carried out under service contracts held with the manufacturers. Faults and their repair are recorded in the LINAC, Simulator, Scanner log books.

Monitoring

The Senior Dosimetry Technician reviews all quality control files weekly and notes any outstanding checks for immediate action or discussion at the departmental machines meeting held every 3 weeks.

Compliance with the departmental procedures for checking and maintenance of equipment is subject to annual audit under the ISO9001: 2008 internal audit programme.

External audit of the equipment processes is provided by BSI as the Trust's ISO9000 assessor to determine compliance with locally defined procedures and ISO9000 requirements. Audit of equipment processes will be undertaken at least once during each 3 year assessment cycle.

7.13.2 Management of imaging equipment

Specific imaging equipment is maintained via the OEM (Original equipment manufacturer), this equipment is maintained and calibrated in accordance with the manufacturer recommendations and is agreed on purchase for the duration of its use. The Head of Department will maintain a record of all equipment within the department together with documented evidence of its maintenance and calibration. Where a fault is detected the OEM will be contacted for repair.

7.13.3 Management of equipment via EBME services

The EBME 3rd party provider covers other electronic/electrical equipment used on wards and ancillary services within CCC. Work on this equipment will always follow manufacturers' recommendations. Repairs may also have to be carried out by the OEM (Original Equipment Manufacturer) with acceptance and check procedures carried out by EBME staff. All documentation used during maintenance and repair is available for access by the MDCM.

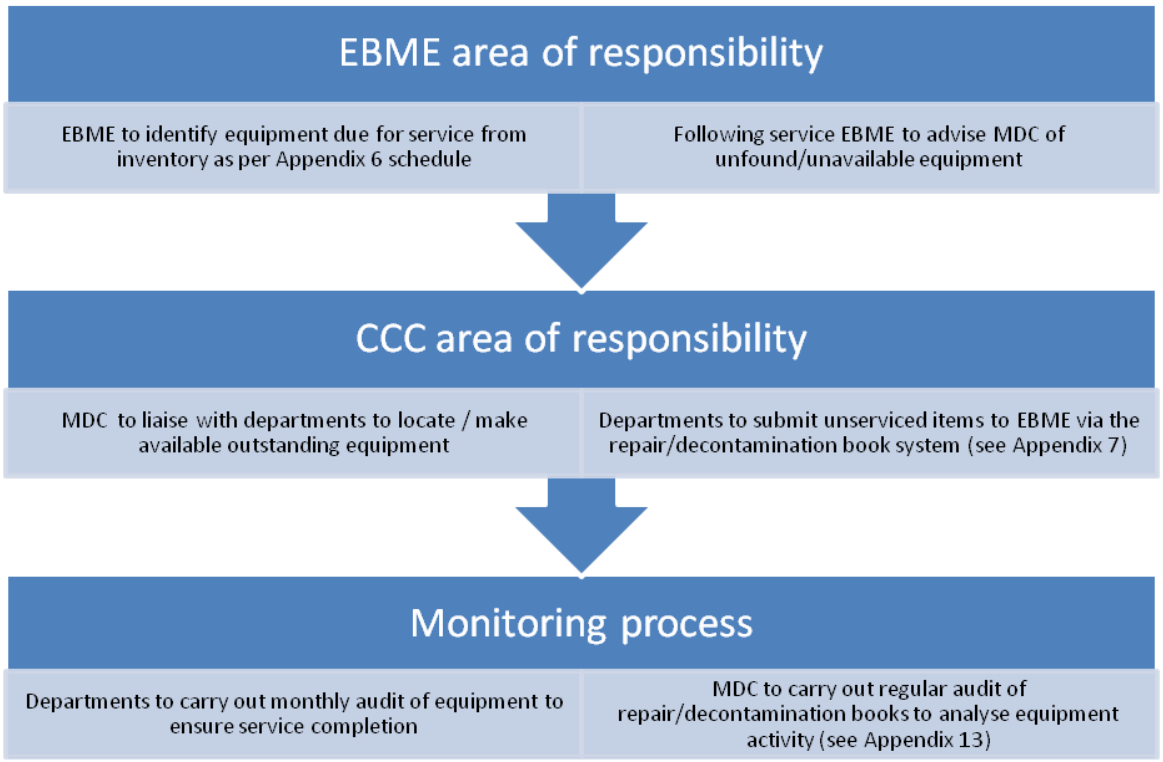
Equipment that is new or added to the medical devices inventory will be advised to EBME by the head of that department for registering, setting up, installation and commissioning according to MHRA Standards. The new items will be added to the database along with new service and test history pages specific to that equipment.

Maintenance

EBME will identify which items of equipment are due for maintenance according to the inventory and stickers applied with next scheduled date for service. To mitigate any risk of equipment not being available during the scheduled maintenance times (e.g. currently being used on a patient or on loan to another department) the EBME department will advise the MDCM details of the equipment unavailable for service. The MDCM will liaise with departmental Medical Device Leads who will be responsible for their location. In addition departmental monthly checks (via the

service sticker on each piece of equipment) will be carried out and any equipment noted as out of service will be submitted to the engineering department by way of the Repair / De-Contamination Book process.

7.14 In Summary



7.14.1 Maintenance records

All electrical, electronic and mechanical medical devices will be recorded on a database (or similar), to ensure appropriate and detailed maintenance can be initiated. Information recorded will include details of calibration, spare parts used, detail and cost of any repair and overall downtime. Maintenance and repair of devices/equipment is carried out in line with the guidance in DB 2006(05). This covers:

- Repair and maintenance process
- maintenance process includes calibration requirements
- Management and monitoring of repair and maintenance
- Training and experience of service personnel
- Selecting a repairer
- Information on repair and maintenance
- Contract with the service provider

- Liability for device repair and maintenance
- Decontamination of equipment returned into store for subsequent reuse and reissue
- Routine maintenance procedures carried out by end-users.

Full maintenance records will be kept for each item of equipment and for historic equipment up to 5 years after it has been discarded. For items maintained via EBME services this data will be held within their database but are clearly noted as the property of the CCC and, as such, can be inspected by them at any time. Items Maintained under CCC Technical Services will be held within the Technical Services Department. All other equipment maintained by outside agencies will be the responsibility of the Head of the Department to record, monitor and provide regular reports on compliance to the MEME.

7.14.2 Repair

In the event of a fault, during normal operational hours the user will contact the EBME 3rd party provider and will identify the location of equipment, its type and the nature of the fault. The EBME 3rd party provider's Account Manager will enter the request into the database and will arrange repair. Before requesting repair or maintenance of a machine the user must indicate in writing any actual/potential biohazard. The EBME 3rd party provider will not accept any equipment for repair unless it is accompanied by a completed Decontamination Certificate (see Appendix 4 for example). The De-contamination Certificate is by way of a two page carbonised book kept within each department. The user must enter the equipment item (including make/model), its asset number, and a brief description of the fault and confirm that the item has been surface cleaned of any actual / potential biohazard. Where the item has been subjected to ingress of any actual / potential biohazard, this must be clearly indicated on the certificate to ensure engineers are aware on investigation into the fault. The user must then sign and date the form and submit one copy to the collecting engineer with the item.

The equipment will be taken out of service immediately, and following request EBME 3rd party provider will respond for investigation within 3 days with a definitive repair within 1 week, the de-contamination sheet must be signed by the attending engineer.

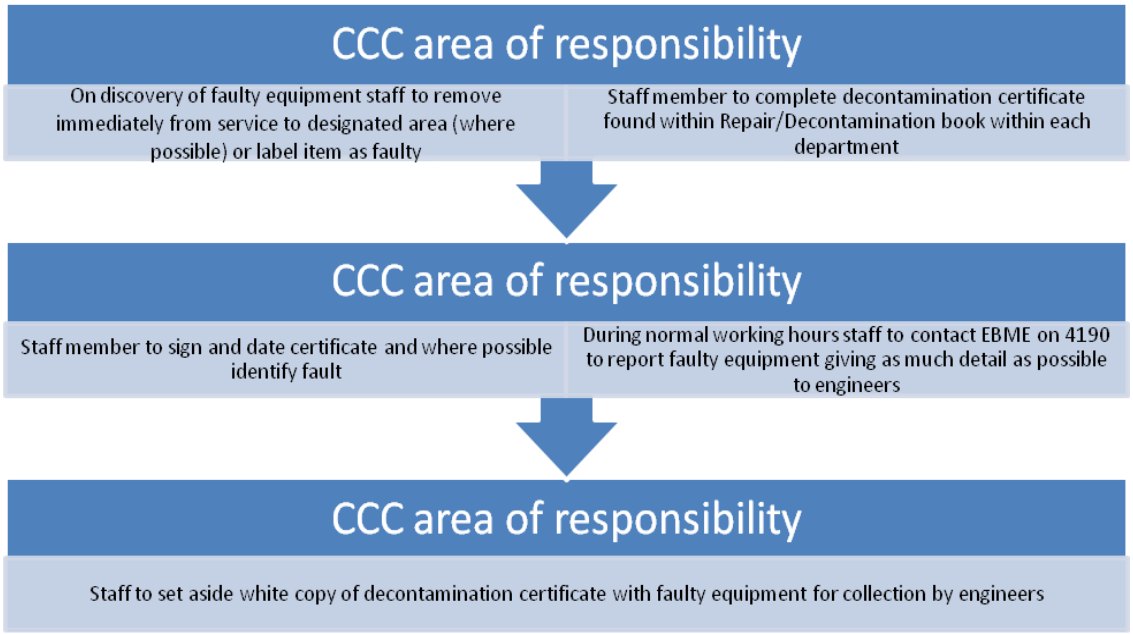
In the event of an urgent request for repair the response time will be within 1 working day.

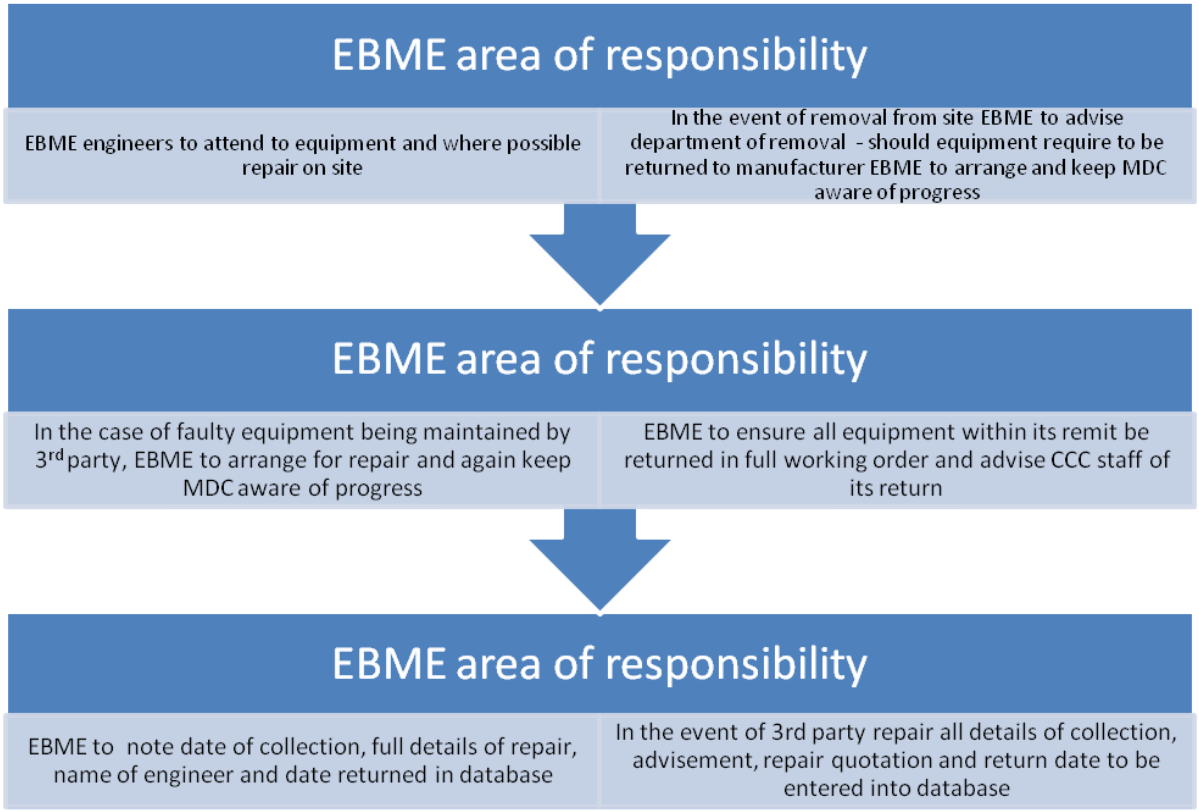
Following maintenance / adjustment the machine will be returned in safe operating condition with clear indication that it has been tested, the accepting CCC staff member will then ensure the item is de-contaminated and returned to operational use and note its return within the Decontamination book.

Repairs to equipment are provided between the hours of 0830 to 1700 Monday to Friday. Most repairs will be carried out on-site (unless under manufacturer's warranty) whilst complex problems may be removed from site for repair.

Where possible, loan equipment will be supplied whilst equipment is being tested and where the user has no other units with which to provide the service, this equipment will be subject to the above processes for acceptance.

7.15 In summary





CCC staff to ensure that all returned / repaired / serviced equipment be decontaminated prior to release for operation.

EBME staff to ensure timely service / repair of equipment as per the agreed terms of the contract.

7.16 Accreditation

All radiotherapy equipment maintenance is accredited with BSI (ISO 9001).

8.0 Decontamination

Heads of Department are responsible for ensuring that all devices intended for repair or maintenance are deemed safe to handle, and decontamination as appropriate has been carried out in accordance with the manufacturers guidelines and the Trust Decontamination Policy. All items will be accompanied by a de-contamination certificate and signed by the attending engineer (as per Appendix 4). Where special forms of decontamination are required, these will be identified and specified by the manufacturers and approved by the CCC Infection Control Team.

Manufacturers of CE marked reusable medical devices are required to provide information on the appropriate process to allow reuse, including cleaning, disinfection, and packaging and where appropriate the method of sterilization of the device to be re-sterilised.

Within CCC, prior to the purchase of any new equipment, (the purchaser) must approach the manufacturers to provide detailed decontamination guidance including the recommended process and (when required) compatible disinfectant solutions.

The Infection Control Team will review the information provided and determine the feasibility of the required decontamination process within CCC.

Risk	Application/Use of Item	Minimum Standard
Low	In contact with healthy skin or makes no physical contact with the patient. e.g. mattresses, furniture, lockers etc.	Cleaning according to the manufacturer's instructions is usually sufficient but disinfection is required if the items have been exposed to blood/body fluids etc.
Medium	In contact with **intact** mucous membranes. Contaminated with highly transmissible microorganisms (e.g. MRSA C.diff) and/or body fluids. Used on immunocompromised patients	Use single use or single patient use whenever possible. Reusable equipment must be cleaned and disinfected (for some items the requirement is to sterilise).
High	In contact with broken skin or mucous membrane or for introduction into a sterile body area.	Cleaning and Sterilisation or single use.

9.0 Replacement of equipment

Replacement will be considered by the Heads of Department in conjunction with the MDCo if any of the following seven criteria apply CCC policy determines the device is no longer serviceable:

- Worn out beyond economic repair
- Damaged beyond economic repair
- Unreliable (check service history)
- Clinically or technically obsolete, or has reached the end of its planned life
- Spare parts no longer available
- More cost-effective or clinically effective devices have become available
- Unable to be cleaned effectively with regard to disinfection and/or sterilization.

Where a replacement item has been identified An Equipment Assessment Form (see Appendix 2) will be completed. Where it is decided by the MEME to forego replacement, a date will be set for re-assessment (e.g. in a year's time).

10.0 Decommissioning of Equipment

Equipment identified for condemnation will be reported to the MDCo with justification and will include details for making safe and any decontamination requirements. Items being de-commissioned or condemned must have an accompanying signed Condemnation Certificate (See Appendix 5).

Where agreement has been met to condemn or decommission an item a copy of the Condemnation Certificate will be sent to the MDCM who will arrange for its removal from the Trust Wide database or for it to be noted as withdrawn, and will inform the MEME. The disposal will be carried out in accordance with any regulations such as WEEE and will be supervised by PropCare, the CCC Estates Department, (please see 'Policy for the Condemning and Disposal of Equipment' policy).

11.0 All Technical Supervisors Are Provided With Appropriate Training

Technical supervisors are "people with technical or managerial roles in medical device management who have engineering, physics or technical training" Within CCC, technical supervisors include:

- Medical Devices & Commodities Manager
- Physics staff (Head of Physics).
- Technical Staff (Head of Technical Services)
- Head of EBME service
- Key Specialist Trainers

Technical supervisors are responsible as appropriate for:

- Organising training for professional users when necessary.
- Ensuring technical staff attend relevant courses.
- Checking the quality of courses.
- Arranging direct supervision of people working with new devices.

The complete process for the purchase and management of medical devices can be found in Appendix 6.

12.0 Audit, Monitoring and Review

Medical Devices Policy Monitoring:

The lead person responsible for monitoring compliance and developing and implementing action plans to rectify non compliance with this policy is the MDCM.

Where non compliance is identified an action plan will be developed by the MDCM and lead assigned to each department, progress against the action plan will be presented to the MEME.

A. Duties:

Lead: Medical Devices & Commodities Manager

Monitoring committee: MEME

A Medical Devices Annual Audit will be presented to the MEME including:

- Number of planned meetings:
- Number of meetings held:
- Attendance table of all members:
- Action plan to address issues on non-attendance of key representatives.

B. Requirement to have a systematic inventory of all reusable medical devices and equipment used within the organisation

Leads: Medical Devices & Commodities manager and EBME

Monitoring committee: MEME

The Medical Devices Annual Report will include a report from the inventory showing:

- Equipment held
- Equipment decommissioned
- Equipment condemned by EBME services
- Equipment reaching the end of its planned lifespan
- Equipment purchased

The MEME will report on equipment activity as part of its core agenda

C. Process for ensuring that all reusable medical devices and equipment are properly maintained and repaired
Lead: Medical Devices & Commodities manager
Monitoring committee: MEME

(Please see detailed process in section 12.0)
An Annual Audit of ward equipment will be undertaken:

- A review of all Repair / De-contamination books covering last 12 months will be undertaken to ensure repairs have been carried out and that equipment has been appropriately maintained.

The MDCo will report on equipment activity as part of its core agenda

For Radiotherapy:
Lead: Radiotherapy Directorate Administrator
Monitoring committee: MEME

- A review of log books for a sample of two mega voltages and one kilovoltage machines.
- A review of quality control checks for a sample of two mega voltages, one kilovoltage and one pre-treatment scanner.
- A review of monitoring processes

Regular reports will be submitted to the Radiotherapy Committee

For Diagnostic Imaging:
Lead: Manager of Imaging
Monitoring committee: MDCo

- A review of the equipment record with regard to evidence of the equipment's maintenance and calibration.

Any actions identified from the above audits will be monitored by the MDCo until completion.

D. Process for checking that calibration of all reusable medical devices are completed within specified time frames
Lead: Medical Devices & Commodities Manager
Monitoring committee: MEME

- See C Above

13.0 Related Documents

The Trust will expect its employees to abide by the requirements of current legislation that would impact upon the use of any medical devices such as DB2006 (5).

14.0 References:

1. Governance in the new NHS. NHS Executive 1999.
2. Managing Medical Devices MHRA DB2006(05)
3. The management of medical equipment in NHS Acute Trusts in England. The National Audit Office 1999.
4. The Health & Safety at Work etc. Act 1974.
5. Equipped to Care - The safe use of medical devices in the 21st century MDA 2001.
6. Devices in Practice - a guide for Health and Social Care Professionals MDA 2001.

APPENDIX 1

Minor Equipment Oversight Group

TERMS OF REFERENCE

Purpose / Objectives	To provide a forum for key stakeholders to oversee and manage all minor medical requirements for the new cancer centre. To ensure timely decision making in line with contractual requirements, to consider and develop risk mitigation strategies as appropriate. To contribute to the development of operational and logistics plans, ensuring resources are in place to enable safe, effective and continuity of service provision. The Group will oversee the Minor Equipment Project Plan, ensuring timely delivery of design information, procurement and transfer decisions, operational commissioning, services and logistics plans. The group will oversee the current management of Minor Medical Devices including policies, replacement programmes risks and datix incidents
Membership	The Group will include: Trust Chairperson – GM Radiation Services PropCare Change Manager Representative Radiotherapy Representative Imaging Representative HO Representative Chemotherapy Representative Integrated Care Representative Physics Medical Devices Co-ordinator IM&T Representative Finance Representative Infection Control Representative Admin, including meeting management and notes
Attendance	The group will invite additional invitees dependent upon agenda items. The group will allow for suitable deputies to attend in the absence of designated members.
Quorum	A quorum shall be the following:

	Trust Chairperson or designated deputy PropCare representative Operational Manager representative Medical Devices Representative
Frequency	In the first instance the group shall meet monthly, as activity creases the meetings will take place as necessitated by the programme. The Chair of the group may call a meeting on an emergency basis with a minimum of three (3) Business Days' notice.
Duties	The procurement of new, or transfer of legacy equipment within the timeframe set out within the project plan. To ensure timely decision making in line with operational requirements, to consider and develop risk mitigation strategies as appropriate. To contribute to the development of operational and logistics plans, ensuring resources are in place to enable safe, effective and continuity of service provision. To contribute to and to oversee the overarching project plan, reporting into the Finance Committee and Joint Steering Group via Major Medical Equipment Committee.
Reporting	Report into the Joint Steering Group and the Finance Committee, identifying progress and any delivery risks via Major Medical Equipment Committee. Reports and updates to be signed off by the Group Chair.
Failure to Gain Agreement	In the event of dispute, the issue will be escalated to the Joint Steering Group for resolution.
Date Approved	

APPENDIX 2

EQUIPMENT ASSESSMENT FORM

Acquisition Date……..... New / Used Assessor Name ……

(PLEASE PRINT CLEARLY)

Equipment Details

Description:		
Model:	Cost:	
Serial ID:	Life expectancy (yrs):	
Manufacturer:	**Order Number**:	
Supplier:	Supplier Contact:	
If modular part of main equipment please note asset No(s)		
Consumables required Yes / No	Item No.	Qty

Owner

Department:	Head of Department:				
Official Location:	Trust Wide Use?	Yes	No	Name:	
Purchase Price:			Charity	Capital	Revenue
Warranty period	months	Services covered:			
Maintenance Contract:	Manufacturer Yes / No	Supplier Yes / No		EBME Yes / No	
Service every:	12 mths	6 mths	3 mths	Other	
Service cost:	£	Inclusive / per item	Parts & Labour	Parts Only	Labour Only
Risk Assessment form completed	Yes / No	Risk Grade			
Purchase / Contract details held by	Department	Medical Devices	Other Please state		

Equipment		Department		Delivery Date
Training provided by:	Manufacturer	Supplier	Staff Member	Other Please state
Awareness Session included in purchase cost				Yes / No
Full Training included in purchase cost:	Yes / No	Training Cost: £		Per day / per session / per delegate

Training Details

Staff grade requiring training:	ALL	2	3	4	5	6	7	8a	8b	8c	8d	9
Staff discipline requiring training:												
Department 'Trainer':	Name:											

Does equipment require awareness session only?	Yes / No	
Is this equipment identical replacement only	Yes / No	
Does equipment require full training?	Yes / No	If so length of session:
Does equipment require full training plus competency sessions?	Yes / No	If Yes, No. of competency sessions:
Does the supplier provide competency sheets?	Yes / No	
Are these competency sheets available electronically?	Yes / No	

Decontamination Details			
Have methods been approved by CCC Infection Control Team?	Yes	No	Name:
If Yes: Are all Users aware of decontamination requirements?	Yes	No	
If No: Please detail below			
Infection Control Team recommendations:			
Equipment approved by:			for Infection Control Team Date:
Equipment approved by:			for Risk Management Team Date:
Equipment approved by:			Medical Devices Group Date:
Equipment approved by:			Medical Equipment Group Date:

	PASS	**FAIL**	**COMMENTS**		
Packaging – check for transport damage					
Equipment – check for physical damage					
Box Contents – as per delivery note					
User Manual Supplied	Yes	No	Is this available electronically?	Yes	No
Service Manual Supplied	Yes	No	Is this available electronically?	Yes	No
Basic Compliance check • CE Marking • Indicators, Fuses, Labelling, Controls, alarms • Calibration			Notes:		
Instrument class markings (If required)					
Full Functional Test					
Full Safety Test (PAT Test)					
EBME advised	Yes	No			

Additional Notes	**Equipment Asset Number** To be obtained via Medical Devices Coordinator / EBME

Delivery

THIS FORM *MUST* BE COMPLETED IN FULL FOR ANY MEDICAL DEVICE INTENDED FOR USE IN CLATTERBRIDGE CANCER CENTRE AND COPY FORWARDED TO MEDICAL DEVICES COORDINATOR

APPENDIX 3

Equipment Trial Assessment Form

Department Requesting Trial:		Head of Department:		
Official Location:	Trust Wide Use?	Yes	No	
Description:				
Date Of Trial – From:	To:			
Model: AM01 Serial No.	Cost:			
Manufacturer:	Life expectancy (yrs):			
Supplier: Dyson direct –	Supplier Contact:			
If modular part of main equipment please note:	N/A	PAT Test Date: PAT Job No:		
Cleaning / Decontamination Details:				
Infection Control Comments: Name:				
Health & Safety Comments: Name: Derry Sinclair				
Departments Included in Trial:				
Ward -Comments Name:				
Physiotherapy - Comments Name:				
Occupational Therapy - Comments Name:				
OPD - Comments Name:				
Diagnostic Imaging - Comments Name:				
R&D – Comments Name:				
Medical Devices – Comments Name: Natalie Atkinson				
Administrative Departments: Name:				
Equipment Accepted for use at CCC	Yes	No		
If no please explain rationale:				
If yes please ensure completion of Equipment Assessment Form				

PLEASE FORWARD COPY OF THIS FORM TO MEDICAL DEVICES COORDINATOR ON COMPLETION

APPENDIX 4

Certificate of Decontamination before inspection, Servicing, or Repair of Medical and Laboratory Equipment or Fixtures in Clinical and Laboratory Areas		**Ward or Department**
This form must be completed by the Officer-in-Charge of the area where the equipment / item described below has been used. If the officer does not feel competent to complete and sign this Certificate, a member of the Infection Control Group should be contacted for advice.		
Description of Item	**Model**	**Serial / ID Number**
Description of fault / Work Request (Please include last settings if available)		
Was this device involved in an adverse incident YES /NO	**Report No.**	

1. This item has not been used in an invasive procedure, nor has it been connected with blood, other body fluids, or other clinical material

a. The item has been externally cleaned, by the procedure recommended in the infection control policy in preparation for inspection servicing or repair	
b. The item has not been externally cleaned, by the procedure recommended in the infection control policy	

If 1b has been completed then complete part 3

2. This item has either been used in an invasive procedure, or it has been in contact with blood, other body fluids, or other clinical material

a. The item has been externally cleaned, by the procedure recommended in the infection control policy in preparation for inspection, servicing or repair	
b. The item has not been externally cleaned, by the procedure recommended in the infection control policy	

If 2b has been completed then complete part 3

3. I was unable to decontaminate this item as recommended in the infection control manual because

4. If you are aware of any remaining potential risks (e.g. chemical or physical) associated with this item, tick the box and describe the nature of the risk

Certifying Officer	**Name (in capitals)**
Date	**Designation**
	Signature

APPENDIX 5

EQUIPMENT DISPOSAL / CONDEMNATION FORM

Details of Equipment:	
Department:	
Make:	Model:
Asset Number:	Serial Number:
Proposed By:	
Name (please print):	Signature:
Approval by Head of Department:	
Date:	Reason for condemnation
Name (please print):	Signature:
Disposal/Condemning: (Delete as appropriate)	
Condemnation Certificate Completed (for specialist condemnation items):	
Date:	Certificate Number:
Name (please print):	Signature:
Is this Equipment to be Replaced: Yes / No (Delete as appropriate)	

Method of Disposal: (Tick as appropriate)		Name	Date Collected
Public Advert			
Sale to Approved Contractor			
Sale to Member of Staff			
Sale Via Auction			
Destruction			

Equipment removed from inventory database:	
Date:	Title:
Name:	EBME Informed: Yes No Via: Telephone / Email / Medical Devices Group
Signature:	Name of EBME Representative advised:

THIS DOCUMENT MUST BE COMPLETED FOR EACH PIECE OF EQUIPMENT CONDEMNED AND FORWARDED TO THE MEDICAL DEVICES COORDINATOR (XTN 5062)

APPENDIX 6

Medical Device Management and Procurement Process

1. Informal assessment of service development need

2. Produce DRAFT outline Business Case (see Appendix 7)
   a) Identify service requirements
   b) Assess suitability of current equipment
   c) Identify new or current equipment to be updated
   d) Identify location for equipment and ensure available space and facilities

3. Consult with Medical Devices & Commodities Manager / EBME / NHS Supplies Service / Suppliers

4. Obtain technical information and obtain, where possible, supplier PPQ – Please ensure details of decontamination regime is included

5. Initial consultation with Health and Safety Advisor

6. Initial consultation with Infection Control Team to assess appropriateness of item

7. Consult / inform Technical Services department

8. Bring proposal to Medical Devices (including Commodities) Committee

9. Populate Equipment Assessment Form (Appendix 2)

10. Obtain sample for trial

11. Complete Trial Assessment Form (Appendix 3)

12. Ensure supplier training for use for those trialling items

13. Ensure appropriate terms for trial

14. Consult Health and Safety Officer

15. Consult Infection Control Team to assess appropriateness of item for infection control

16. Complete appropriate Risk Assessment (See appendix 8) and forward to Medical Devices & Commodities Manager for record

17. Ensure that each department for whom the equipment is intended or could be used is able to assess

18. If successful trial completed agree training schedule for all intended users complete with details of any competencies required (this is the responsibility of the Head of the Department for which the equipment is to be used – sample competency sheet to be forwarded to Medical Devices & Commodities Manager).

19. Present completed assessment and business case to Mobile Electrical Medical Equipment (MEME) Group.

20. Medical Devices & Commodities Manager (and/or Project Team Leader) to submit recommendations to Mobile Electrical Medical Equipment (MEME) Group for financial approval.

21. Medical Devices & Commodities Manager and EBME services to be advised of intended delivery of equipment (all electronic / electrical equipment to be delivered to EBME for acceptance and full testing)

22. On delivery of equipment to CCC all intended users to be fully trained prior to equipment being made operational (details to be retained by the Head of Department for which the equipment is to be used)

23. During its lifetime equipment is to be fully serviced and maintained according to the manufacturer's instructions and in line with CCC infection control guidelines.

24. Where equipment is not maintained via EBME services the Head of Department will keep robust data on service and maintenance and will provide regular updates to the Medical Devices & Commodities Manager

25. The equipment is to be used for the purpose in which it was designed and no modifications are to be made without consulting the manufacturer and appropriate assessments having been made

26. The equipment will not be used by any persons who have not been trained in its operation

27. When equipment is deemed to be operationally unsound or outdated it will undergo full external decontamination - The user deeming the equipment to be of no further use to complete a condemnation form giving full details (Appendix 5)

28. The condemnation form will then be approved by the owning Head of Department and a copy forwarded to the Medical Devices & Commodities Manager. It is the Medical Devices & Commodities Manager's role to inform EBME of the condemnation in order for it to be removed from the Trustwide data and asset bases

29. The equipment along with its condemnation form will then be collected by the Medical Devices & Commodities Manager (where possible) and given to CCC Technical Services Department for disposal in accordance with its manufacturer guidelines

30. The condemnation will be informed to the Mobile Electrical Medical Equipment (MEME) Group by the Medical Devices & Commodities Manager and where the equipment has been deemed unsafe for purpose a report will be sent to the risk assessment group for dissemination.

APPENDIX 7

The Clatterbridge Cancer Centre NHS
NHS Foundation Trust

BUSINESS CASE

<Project Title>

Release Status: DRAFT, REVIEW, FOR INFORMATION or FINAL

Author: Insert Name

Date:

Filename & Version: Insert details

Project ID:

Document Location

This document is stored in the following location:

Filename	
Location	

Revision History

This document has been through the following revisions:

Version No. Changed	Revision Date	Filename/Location stored:	Brief Summary of Changes

Authorisation

This document requires the following approvals:

AUTHORISATION	Name	Signature	Date
Medical Equipment Group			
Medical Devices Group			
Head of Department / Requisitioner			

Distribution

This document has been distributed to:

Name	Title	Version Issued	Date of Issue

Related Documents

Summary of filenames and locations of related documents:

Document Type	Filename/Location stored:
Project Mandate	
Project Brief	

Contents

APPENDIX 8

RISK ASSESSMENT FORM

Dept:	**Assessment date:**
Lead Assessor/s:	**Who/What is at risk:**

RISK INFORMATION

Summary of risk (brief description to populate the Trust Risk Register):

Description of risk (background information / detail to give risk context):

Existent control measures: (i.e. what is currently in place to reduce the risks)

Risk Scoring- see risk matrix attached

Impact score =

Likelihood score =

Risk Score (impact x likelihood)

A Risk Mitigation Plan must be attached for all risks 15 and over

Impact descriptor used (e.g. finance, radiation etc) =

Action Plan

Action	Responsibility	Due Date	Progress	Completed date

Please send a copy to: the Risk Management Facilitator, CGST

Risk Grading:

1. Impact: use table 1 to determine the Impact score. In the case of incidents, complaints & claims, this is the actual consequence (what actually happened). In the case of proactive risk assessments, it's the potential consequence (i.e. what could potentially happen). All events may have one or several types of impact (e.g. patient injury, financial etc). The score used as the overall impact score is the highest
2. Likelihood: Use Table 2 to determine the Likelihood score. This is the chance of the impact score described above will occur or recur.
3. Risk Score: Use Table 3 to calculate Risk Score. Multiply the Impact score with the Likelihood score. This will give a value between 1-25.
4. Detail actions in the action plan to mitigate or eliminate the risk.
5. Table 4 details the management of the risk depending on the risk score.

TABLE 1: The descriptors and levels of Impact.

	1	2	3	4	5
	None	**Minor**	**Moderate**	**Major**	**Catastrophic**
Patient injury (emotional, physical, psychological, loss of function)	No injury or identifiable damage	Mild injury likely to resolve in 1 month	Some injury that will resolve in a year	Serious injury with prolonged disability	Unexpected death or significant permanent disability
Staff / visitor injury	No injury or minor injury not requiring first aid	Mild injury requiring first aid	Injuries that last for more than 3 days	Major injuries reportable under RIDDOR	Unexpected death or significant permanent disability
Control of infection	Minor microbiological contamination not coming into contact with patients, staff or public	Contamination or hospital acquired colonisation affecting one or more individuals	Contamination causing hospital acquired infection of one or more individuals	Contamination or hospital acquired infection causing clinical impact to patient / staff or closure of the ward	Contamination or hospital acquired infection causing unexpected death or significant permanent disability or multiple ward or hospital closure
Possibility of complaint or litigation	No possibility of complaint or litigation	Slight possibility of complaint or litigation	Likely complaint or litigation	Claim above excess level. Justified multiple complaints	Multiple claims or single major claim
Objectives / project slipping	Insignificant project slippage, cost increase. Barely noticeable reduction in scope or quality	Minor project slippage. Minor reduction in scope or quality. <5% over budget	Serious over run on project Reduction in scope or quality 5-10% over budget	Project in danger of not being delivered. Failure to meet secondary objectives 10-25% over budget	Unable to deliver project Failure to meet primary objectives >25% over budget.
Service / business interruption	Loss / interruption up to 1 hour	Loss / interruption up to 4 hours	Loss / interruption up to 8 hours	Loss / interruption up to 2 days	Loss / interruption more than 2 days
Workforce capacity / capability	Service delivery not compromised	Service delivery compromised at a minimum short term level (1 day) Unsatisfactory staffing level (below minimum level and skill mix)	Service delivery compromised / reduced. Ongoing unsafe for 2-5 days	Service delivery compromised / reduced. Ongoing unsafe for 5-10 days	Major service disruption / inability to provide service due to significant lack of staff
Financial	No obvious / small loss.	Financial loss less than (£10K)	Financial loss (£10-50k)	Financial loss (£50 - £250K)	Financial loss (£>250k)
External inspections	No adverse comments / non compliances	Recommendations given	Challenging recommendations	Enforcement action / critical report	Severely critical report / improvement notices / removal of licence
Adverse publicity / reputation	Rumours (internal / external) no impact on reputation	Local media attention – short term and retrievable	Local media attention – ling term – impact on reputation resulting in detrimental impact upon perception of stakeholders	National adverse publicity or significant negative publicity relating to Trust practice which has impact on business continuity	National adverse publicity resulting in significant detrimental impact on business. Full public enquiry.
Estates infrastructure	Minor service inconvenience. Able to be resolved in 1 day. Effects small part of hospital	Temporary loss of service in single area. Safety breach that could lead to	Prolonged loss of service to single areas that would result in area closure. Safety breach that could lead to	Prolonged loss of service to single or multiple areas that would result in area closure. Safety breach that could lead to	Hospital wide disruption to clinical services.

		injury but risks able to be controlled.	serious injury and able to be controlled.	serious injury and risks not able to be controlled	External safety warning of major danger to staff / patients.
Compliance	No or minimal breach of guidance / regulatory or statutory duty.	Breach of guidance / regulatory or statutory duty. Reduced performance but able to resolve. Unresolved.	Breach of guidance / regulatory or statutory duty. Reduced performance rating if unresolved.	Breach of guidance / regulatory or statutory duty. Improvement notices. Low performance rating	Breach of guidance / regulatory or statutory duty. Prosecution. Complete systems change required. Severely critical report.
Information governance	Less than 5 people affected or risk assessed as low e.g. files encrypted	Serious potential breach and risk assessed high e.g. unencrypted clinical records lost. Up to 20 people effected	Serious breach of confidentiality e.g. up to 100 people effected	Serious breach with either particular sensitivity or up to 1000 people effected	Serious breach with potential theft.
Radiation	None or minimally increased dose to staff or patients	Some increase in dose to one or more individual(s) (non-patient) Some increase in patient dose (for <30% of treatment fractions)	Dose Investigation Levels exceeded for one or more individual(s) (non-patient) Impact on dose for many treatment fractions or for several patients Significant increase in patient dose (non-treatment) (>50%)	Annual Dose Limit exceeded for one or more individual(s) (Reportable) >5% impact on treatment dose (full course) Impact on treatment dose for many patients (>5%) Major increase in patient dose (non-treatment) (>3x)	Critical dose to one or more individual(s) >20% impact on treatment dose (single fraction) or 10% (full course) (Reportable) Impact on treatment dose for very many patients (>15%) Reportable increase in patient dose (non-treatment)
Patient experience / outcome	Unsatisfactory patient experience not directly related to patient care	Unsatisfactory patient experience readily resolved	Mismanagement of patient care, short term effects (less than a week)	Serious mismanagement of patients care, long term effects (more than 1 week)	Totally unsatisfactory patient outcome or experience.

TABLE 2: Likelihood.	**Descriptor**	**Proposed description**
1	Rare	May occur in exceptional circumstances, not expected to occur.
2	Unlikely	Unlikely to occur, could occur on an infrequent basis
3	Possible	Reasonable chance of occurring. Expected to occur a few times.
4	Likely	Will occur in most circumstances, expected to occur in most circumstances. However, not a persistent issue. No issues of custom and practice
5	Certain	Most likely to occur than not, expected to occur frequently / expected to occur in most circumstances. Is a constant threat, is custom and practice.

TABLE 3: Risk grading matrix:

***Impact*→** **↓ Likelihood**	None	Minor	Moderate	Major	Catastrophic
Almost certain	5	10	15	20	25
Likely	4	8	12	16	20
Possible	3	6	9	12	15
Unlikely	2	4	6	8	10
Rare	1	2	3	4	5

TABLE 4: Management of Risk:

	High risk (15 and over) Managed by risk owner (usually departmental manager) with oversight by an executive director Immediate action to remove or reduce the risk Highlight action plan contained in risk register with defined timescales and target reduction to reduce or remove the risk with full risk mitigation plan developed by risk owner. Risk reviewed at least monthly. Risks included in departmental reviews. Risks reported monthly to Trust Board with risk mitigation plans and monthly reviews.
	Moderate risk (9-12) Managed by Departmental manager Urgent action to remove or reduce the risk Action plan contained in risk register with defined timescales to reduce or remove the risk Risk reviewed at least quarterly. Risks included in departmental reviews. Risks reported to Integrated Governance (or other relevant Board committee) quarterly.
	Low risk (4-8) Managed by departmental manager Action cost effective in reducing risk Actions contained within risk register, reviewed minimum of 6 monthly
	Very low risk (less than 4) Managed by routine procedures Action if inexpensive / easy to implement Actions contained within risk register, reviewed minimum of annually

Risk Mitigation Action Plan For Red Risks Scoring 15 or over

Current Risk: Define risk as per risk register / assurance framework

Risk owner

Current residual risk score (taking into account existing controls and assurances)**:** Impact: x, likelihood: x score x

Planned risk score with timescale which action plan aims to deliver.

Background
Further description of risk, where risk originated (e.g. link to specific corporate objective in assurance framework)

Current Position
Explanation of why risk is currently scored high.

Outstanding Actions (controls or assurances)
Actions that already exist in risk register / assurance framework.
Add information on why action has not been delivered. Add new timescale for action to be completed.

Further Planned Actions (controls or assurances)
Add new actions with timescale and method of monitoring delivery

Recommendation to Trust Board
Add any recommendations where a revision of the risk score is proposed.