Management of Medical Equipment Policy for Staff

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Contents

1 Introduction

This policy replaces the Management of Medical Equipment Procedure and reflects the guidelines set out in Device Bulletin DB2006 (05) Managing Medical Devices published by the Medicines and Healthcare products Regulatory Agency (MHRA) that can be found on line here.
http://9.200.150.6/internal/healthcare/support/medphysics/documents/ManagingMedicalDevicesDB200605.pdf

2 Definitions

a) Medical Devices

A medical device is any healthcare product, instrument, apparatus, appliance, material or other article, excluding drugs, used for the purposes of diagnosis, prevention, monitoring, treatment or alleviation of disease or injury or handicap.

Medical devices do not include drugs, estates related equipment such as beds, catering and laundry equipment, computing equipment unless it is physically linked to patient connected medical equipment.

b) Medical Equipment

Medical equipment is a subset of medical devices and is defined as all devices that are connected to the patient as part of their treatment and care in hospitals and health centres, and devices used for diagnostic purposes. Within NHS Shetland, renal dialysis equipment, X-Ray imaging equipment, point of care test equipment, consumables such as syringes and dressings do not come under the remit of the Medical Physics department. Separate arrangements are in place for these devices.

3 Medical Equipment Management

The purpose of Medical Equipment Management is to ensure that the equipment available:

Is suitable for the intended purpose.
Is understood by the users.
Is in a safe and serviceable condition.
Meets safety and quality standards and requirements
Meets HAI requirements including cleaning, decontamination and reprocessing.
Is stored and used in appropriate and controlled conditions.
Satisfies the above criteria in a cost effective manner.

The maintenance of a complete and up-to-date inventory of equipment is an essential requirement, not only for effective equipment management, but also for accounting purposes. Unused or obsolete equipment is a continual drain on maintenance resources. The opportunity should be taken to dispose of or re-deploy any equipment that is redundant in its present location.

Equipment management embraces the following functions:

Justification of need.
Selection of new equipment.
Ordering.
Acceptance testing and commissioning.
Inclusion into the equipment database for planned maintenance schedules and rolling replacement.
Maintenance.
Decommissioning and disposal.
Replacement.

Note: General Practitioners (GPs) are responsible for ensuring that the equipment they use is properly maintained. This may be carried out either by the in-house service provided by the Medical Physics Department at the Gilbert Bain Hospital (by Service Level Agreement SLA) or by external service providers.

4 Acquisition of New Medical Equipment

a) Justification of Need

All requests for new equipment must be justified to ensure that the equipment is suitable for the proposed use and will be fully utilised.

The functional requirements should be defined precisely and with as much detail as possible. Care must be taken not to specify a performance better than is needed although future developments during the lifetime of the equipment should be considered.

When requesting new or replacement equipment with a value of £100 to £4999.99, a "Request for Trial, Purchase or Replacement of **Non-Capital** Equipment or Small Work" form should be completed and submitted to the Director of Finance. These are then discussed and prioritised by the Minor Works and Equipment Group (MWEG).

The form for this can be found at: -
http://9.200.150.6/internal/healthcare/support/finance/documents/EPGRequestForm.doc

When requesting new or replacement equipment with a value of £5,000 and above, a "Request for Trial, Purchase or Replacement of **Capital** Equipment" form should be completed and submitted to the Chief Medical Physics officer having been countersigned by the relevant Director. These are then discussed and prioritised by the Clinical Services Management Team (CSMT).

The form for this can be found at: -
http://9.200.150.6/internal/healthcare/support/medphysics/documents/CapitalMedicalEquipmentRequestForm.doc

The selection and purchase process can only be carried out once the case of need has been approved, thus eliminating any unnecessary work.

In granting approval, the whole life cost of the equipment should be considered, not just the initial purchase price. This must include the cost of maintenance, training, disposables and consumables.

b) Selection of New Equipment

All new medical equipment must be CE marked and comply with relevant standards. It should be specifically designed for the purpose for which it will be used and be safe to use. Spares and service information must be available so that the equipment can be maintained.

A range of equipment that appears to satisfy the functional requirements should be identified. Standardisation of equipment should be taken into account and detailed specifications should be obtained from the supplier or manufacturer for items identified as potentially suitable.

Cleaning, decontamination, sterilisation and reprocessing information is required in order to ensure that manufacturer's guidelines can be followed and any additional cost implications can be fully evaluated at an early stage. The Senior Charge Nurse or Head of Department will contact the Infection Control Team for advice. The Infection control Team will then provide advice on the suitability of the equipment with reference to cleaning, disinfection, decontamination and reprocessing. The Clinical Services Management Team or Minor Works and Equipment Group will decide if procurement is to proceed.

The final selection of equipment should be made in close consultation with those responsible for the clinical use of the equipment. Advice should be sought from the Chief Medical Physics Officer and Finance Department with regard to technical specifications and financial planning.

c) Standardisation

The Medical Physics Department, wherever practical, operates a policy of standardisation on purchase of Medical Equipment. This ensures that unless there are valid clinical and technical reasons, similar and up to date models of equipment from the same supplier are purchased in order to ensure:

Ease of user training
Reduction in Risk achieved by the users being familiar with type of equipment
Availability of in-house expertise and ease of servicing
Cost benefits in terms of purchase of consumables and administration sets
Cost reduction if equipment is to be placed on external contract
Rapid exchange of equipment from other areas in the event of equipment failure

In the event of more up to date equipment being introduced by other suppliers, evaluations will take place and equipment standardisation reviewed.

d) Ordering

It is essential that the Chief Medical Physics Officer authorises all orders for medical equipment to ensure that best possible value can be achieved and that technical manuals, service information and training where appropriate, can be included in the order at the time of purchase.

To ensure proper redress in the event of dispute, the order should be drafted to clearly define the following:

- Items to be supplied.
- Compliance with appropriate relevant standards.
- Installation and commissioning work to be carried out.
- Agreed acceptance procedure, including any training required.
- Full details of price, settlement terms and discounts.
- Delivery dates.
- Other conditions of supply.
- The person or department to which the equipment should be delivered. This will normally be the Medical Physics Department.

e) Acceptance Testing and Commissioning

Acceptance testing and commissioning encompasses:

- Checking that all equipment and accessories ordered including operating and service manuals have been delivered complete and undamaged.
- Assembling and commissioning the equipment.
- Testing the equipment for electrical safety.
- Checking that the equipment functions as specified.
- Entering the equipment details into the database, thereby ensuring it is regularly maintained and safety tested, in accordance with manufacturer's instructions. This also aids traceability and product recall.
- Retaining a copy of the user instructions for reference.
- Clearing the invoice for payment only when this process is complete.

For this to take place it is necessary for all new equipment to be delivered directly to the Medical Physics Department along with the delivery note. Medical equipment must not be used until it has been checked, tested and logged by the Medical Physics department.

5 User Responsibilities

a) Training

In each ward or department, an individual (usually the Head of Department) should be identified as the Department Equipment Controller. This person will take responsibility for monitoring the whereabouts of their equipment, ensuring that user instructions are available and that users receive appropriate training. Training needs should be identified through the Personal Development and Review process and referenced in the electronic Knowledge and Skills Framework (e-KSF).

Each individual practitioner is accountable for the safe use of medical devices they use and therefore any medical device should only be used/checked by a qualified practitioner who has received training appropriate to the device selected. Instruction manuals should be available in each area and reference should be made to these for further clarification if necessary. A library of user instruction manuals is maintained on the Medical Physics Intranet site at: -
http://9.200.150.6/internal/healthcare/support/medphysics/manuals.asp

b) Precautions

Disassembly, repair or modification of medical devices must only be carried out by qualified staff from the Medical Physics Department.

Devices in use should be inspected regularly, by the user, to ensure they are continuing to function as expected.

Devices that have internal rechargeable batteries should be kept on charge when not in use.

Hospital and community medical devices should only be used with mains leads with **Red Mains Plugs**.

Only mains extension leads with **Red Mains Plugs** should be used with hospital and community medical devices. It is not permitted to use any other mains extension leads as this may compromise the electrical safety of the device.

Temporary sticky labels should not be attached to medical devices as the adhesive sticks to the device. This contaminates the device and can cause malfunction. It may also cause confusion if the label is not removed.

It is imperative that the correct device for the job is used in the prescribed manner, in accordance with the manufacturer's instructions and for the purpose for which it was designed. Equipment must not be used or modified to perform any other function or for any other purpose than that intended by the manufacturer.

6 Dealing with Medical Equipment Failure

a) Dealing with a Medical Equipment Failure

If a medical device is faulty or is suspected of being faulty or is not operating as expected or is giving unexplained false alarms, then a qualified practitioner should attend the patient immediately. All appropriate action should be taken to ensure the safety of the patient. The device should be deactivated prior to investigation, in order to ensure that there is no further compromise to patient safety. The device requires a complete check, referring to the manual if necessary, before being reactivated. If, after investigation, the practitioner is not completely satisfied that the device is fully functional, it must be replaced with another one if available, and sent to the Medical Physics Department for repair.

The practitioner who observed the fault should make a note of any readings, settings, controls etc as these may aid the Medical Physics Department in fault diagnosis.

b) Reporting Adverse Incidents Involving Medical Equipment

An adverse incident is an event that has produced, or has the potential to produce, unexpected or unwanted effects involving the safety of patients, users or other persons. All adverse incidents should be reported and recorded according to the Procedure for Reporting Defective Equipment at:-
http://9.200.150.6/documents/pphandbook/documents/ReportingDefectiveEquipment.pdf

Adverse incidents involving biomedical equipment must be reported immediately to the head of department who will then contact the Chief Medical Physics Officer as soon as possible.

A note should be made of the equipment ID number (a six digit number usually below the barcode on a white label), any readings, alarms, and settings. The equipment, including any leads, probes and administration sets, must be clearly marked and isolated from use. This equipment must then be taken to the Medical Physics department for further investigation. It should be clearly stated that the equipment has been involved in an adverse incident so that it can be dealt with urgently and thoroughly.

The equipment details must be entered into the space provided on Datix incident reporting system.

c) Sending Medical Devices to Medical Physics for Repair

Cleaning and Decontamination

The equipment and accessories must be assessed to determine if they have been contaminated. The exterior of the equipment, accessories and any user accessible parts must be cleaned and decontaminated. Where specific guidelines for the decontamination of an item of equipment are identified in the user instructions, these should be followed.

General Guidelines

Note: It is very important that electrical equipment is not unduly wetted. Switch off and isolate from power source. Observe Control of Substances Hazardous to Health (COSHH) precautions.

Where only dust is present on the surface of the equipment, a dusting with a cloth dampened with a general-purpose detergent solution should be sufficient, followed by a thorough drying.

If the equipment has been in contact with a known infected patient or has visible signs of blood or other bodily materials, it must be thoroughly cleaned and disinfected.

If you suspect or know there is radioactive or hazardous chemical contamination on the equipment, you must use the appropriate methods of cleaning.

If you have any doubts about the correct method or what cleaning materials to use, then you should seek the advice of the Control of Infection Team.

Remember: Thorough cleaning always precedes the use of antiseptics or disinfectants.

Covers for pressure area care mattresses should be removed from the mattress and sent for cleaning. Do not send mattress covers to the Medical Physics Department.

Fill in a Blue Requisition Form (see appendix A)

The person who first observes the fault should complete this form. Most of the form is self-explanatory. The Certificate of Cleaning **must** be completed and signed. Tick one box from each group.

A completed blue requisition form **must** accompany all equipment sent for repair.

Any equipment received for repair, which is not accompanied by a completed certificate of cleaning, will be returned to the originating ward or department for further investigation and if necessary, remedial action.

If the equipment has been contaminated, and decontamination has not been possible, i.e. beyond user accessible parts, then the WARNING box, on the certificate of cleaning, should be ticked so that personal protective equipment can be used during repair, thus reducing the risk of exposure to staff.

Any leads and accessories should accompany the equipment.

7 Maintenance of Medical Equipment

a) Maintenance

Only equipment that is the property of NHS Shetland and is logged onto the Medical Physics equipment management database will be maintained by the Medical Physics department.

Maintenance involves:

Carrying out planned maintenance, in order to reduce the incidence of breakdowns.
Calibrating the equipment to ensure it is accurate and can be relied upon.
Testing the equipment for electrical safety on a regular basis in order to comply with the Electricity at Work Regulations
Carrying out repairs on the equipment or arranging for equipment to be repaired by the manufacturer.
Maintaining adequate records of the service history of the equipment throughout its lifetime and retaining records in accordance with current guidelines.

b) Medical Device Maintenance Records

A detailed record of maintenance and repair is kept in the Medical Physics Department, for each item of medical equipment. The following minimum dataset is included on the Medical Equipment Database in electronic format.

Individual identification number
Location
Department/Speciality
Make
Model
Supplier
Purchase/Acquisition Date
Purchase Cost
Anticipated Replacement Date
Maintenance Intervals
Planned Maintenance Dates
Full Service History

c) Return to Service after Maintenance

When a device has been to the Medical Physics Department for service, it will be returned to the users with "Serviced" tape (see appendix B) over the main controls. This is to alert the **first user** to check the equipment and settings, where appropriate, prior to use. Once this has been done, the tape **must** be removed and discarded. The tape acts as a warning to the first user and should **not** be removed by anyone else.

8 Decommissioning And Disposal

It is necessary to identify, in advance, when equipment will need to be replaced. This need is based on the age and serviceability of the equipment. Planned replacement means that equipment is removed from service and decommissioned at the end of its useful or economic life. The Medical Physics Department is responsible for decommissioning. If equipment is considered unsuitable for further use then the Medical Physics Department should be notified. The equipment can then be either redeployed elsewhere or deleted from the equipment management system and disposed of in the most suitable manner in accordance with current guidelines. Please refer to the Procedure for Condemnation & Disposal of Equipment, this can be found here: -

http://9.200.150.6/documents/pphandbook/documents/ProcedureforCondemnationandDisposalofEquipment.pdf

Medical equipment should not be disposed of without prior authorisation from the Medical Physics Department.

Appendix A

MEDICAL PHYSICS DEPARTMENT

EQUIPMENT REPAIR AND TECHNICAL SERVICES REQUISITION

HOSPITAL HEALTH CENTRE	WARD DEPT.	DATE
I.D. NUMBER (Below Bar Code)	EQUIPMENT DESCRIPTION	

EXACT NATURE OF FAULT / SERVICE REQUIRED. To be completed by the person who observed the fault.

CERTIFICATE OF CLEANING

For servicing of equipment, this section **MUST BE COMPLETED**. Tick one box from each group (4 ticks)

HAS THE EQUIPMENT BEEN IN CONTACT WITH:

BIOHAZARDOUS MATERIAL	HAZARDOUS CHEMICALS	RADIOACTIVE MATERIAL
YES ☐ NO ☐	YES ☐ NO ☐	YES ☐ NO ☐

☐ I certify that this equipment is clean. Any necessary cleaning/decontamination has been carried outin accordance with sterilisation and disinfection policy published by Shetland Hospitals and Community Services Unit.

☐ WARNING : It has not been possible to fully clean and decontaminate this equipment, extra precautions should be taken during servicing.

SIGNED .....

PRINT NAME	DESIGNATION	PHONE

Appendix B

SERVICED	**CAUTION PLEASE CHECK THIS EQUIPMENT CAREFULLY BEFORE USE REMOVE TAPE ONLY AFTER CHECKING**

1. Assessment of Impact

On the basis of all the information available and the collective understanding of the legislation covering the main equality communities of people, the Chief Medical Physics Officer reached the following conclusions on the likely impact the current structure and delivery of Management of Medical Equipment Policy will have on those communities.

Race
It was concluded that the impact on this community would be positive. The rational for this is that the Management of Medical Equipment Policy was developed to protect all employees, patients and anyone else who could potentially be affected by medical equipment. This inclusive approach to medical equipment management would be lawful in terms of the general and specific duties on race equality to eliminate discrimination.

Disability
The Chief Medical Physics Officer concluded that the impact on this community of people would be positive. The rationale for this is that **all** equipment is managed and maintained to the same high standards and in compliance with current legislation and best practice. This would be lawful in terms of the general and specific duties on disability equality to eliminate discrimination as a result of a person's disability.

Gender and Sex
In similar terms to the two previous areas, the Chief Medical Physics Officer concluded that there would be no impact on the grounds of gender or sex as equipment is not gender or sex specific. At the time of conducting this Impact Assessment and writing this report, such an impact would be lawful in terms of the general and specific duties on gender equality to eliminate sex discrimination.

Sexual Orientation
In relation to this community of people the Chief Medical Physics Officer took the view that there was potentially no impact on the grounds of sexual orientation for similar reasons stated above.

Such a situation will be lawful in terms of the legal obligations to eliminate discrimination on the grounds of a person's sexual orientation.

Faith & Religion
The Chief Medical Physics Officer concluded that for this community of people there was no impact on the grounds of faith and religion for similar reasons to those stated above.

It is expected that such a situation would be lawful in terms of the legal obligations to eliminate discrimination on the grounds of a person's faith or religion.

Age
The Chief Medical Physics Officer concluded that for this community of people there was a positive impact as a suitable range of equipment was procured and maintained for all age groups. This situation would be lawful.

Mental Health
The Chief Medical Physics Officer believes that there would be positive impact. This would be lawful in terms of the general duty to eliminate discrimination on grounds of disability.

2. Need for changes in the Policy

Having cognisance of the findings presented above, it is the conclusion of the Chief Medical Physics Officer, endorsed by the Diversity Task Force that the Management of Medical Equipment Policy complies with current equality and diversity legislation and good practice and no changes to the existing policy are currently required.

3. Consultation

The findings of this Equality Impact Assessment will be posted on the E&D section of the NHS SHETLAND web site and flagged as available for comment.

Where requested, the NHS SHETLAND Equality & Diversity Lead will meet with organisations, groups or individuals who prefer to debate the content of the report and offer comment on it in a direct exchange.

4. Monitoring & Review

Arrangements for monitoring and reviewing the impact, planned and unplanned, of this Management of Medical Equipment Policy will be put in place as required, following and taking account of what we learn from comments and feedback received on these published findings.

Signed ..... Graham Southern

Designation Chief Medical Physics Officer

Date 7 February 2011