



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Medical Equipment Management Policy

Procedure No. 114

	Print Name	Title	Date
Prepared by	Clinical Engineering		1st June 08
Reviewed by	Bernard Ryan	Clinical engineering Technician	1st June 08
Corporate Authorisation	J.Mc Namara	T.S.O.	1st June 08

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1.0 Policy Statement.

The Clinical Engineering Department of the HSE Mid Western Regional Hospitals, Network 7 Area, has primary responsibility for the management of Biomedical assets. With the increasing availability and demands for new technology in the medical sector, it is the aim of the department from within the financial resources available; to ensure that the highest level of technology is available for clinical use in the provision of quality patient care. In addition, the department aims to ensure that the highest standards of equipment safety, risk management, user satisfaction, clinical technical support and financial efficiency are realised in the management of this critical application technology throughout the life cycle of the equipment.

2.0 Policy Purpose.

The following equipment management policy document will contribute to the process of ensuring the efficient and safe use of medical technology throughout the Mid Western Regional Hospitals and that value for money is realised in this process.

2.1 Aim

- ❖ To address IMB Medical Device Safety Notices SN2003 (08) “Equipment Management”, SN2003 (09) “Equipment Management Basic Principals” and SN2006 (03) “The Procurement and Commissioning of Medical Equipment for Hospitals”.
- ❖ To advise hospital management on the status of existing equipment for replacement and the requirements of new equipment for expansion / new services.
- ❖ Implement and operate an equipment management system that will ensure the safe management of biomedical equipment from cradle to grave.
- ❖ Medical equipment used within the Mid Western Regional Hospitals complies with the recommended standards particularly those pertaining to safety.
- ❖ Where possible a standardisation of common types of equipment is achieved, thus contributing to:
 - Risk management.
 - VFM.
 - Facilitate ease of use.
 - User training.
 - Equipment management.
- ❖ To keep maintenance and revenue costs to a minimum and that value for money is realised in this process.
- ❖ For Capital Projects, to provide advice on biomedical technology and compatibility with existing technologies throughout the network.
- ❖ To facilitate compatibility of medical technology between primary care and secondary care.

2.2 Risk Management

Risk Management is a systematic process of risk identification, analysis, evaluation and correction of potential and actual risks to a patient, visitor, and member of staff or property. Efficient risk management is based on a partnership between the organisation and the individual healthcare professionals. Consequently it is necessary that the “Medical Equipment Management Policy” be adopted by the clinical networks as a formalised procedure for the management of medical equipment.

Pertaining to Risk Management the policy document covers the following areas: -

- Requirement for Acceptance Testing procedure.
- Standardisation of common devices to facilitate familiarity.
- Requirement for decontamination and infection control procedures.
- Ensuring the User is prescribed in best practice in the use of equipment.
- Requirement for documented clinical user training.
- Maintenance and servicing of equipment.
- Equipment tracking and equipment records.

2.3 Infection Control.

The protection of both patient’s staff and visitors from the transmission of infection from medical equipment requires the adoption of safe systems of work. Written procedures should be available to ensure that all items are decontaminated to manufacture guidelines and are approved by the infection prevention & control committee. All equipment removed from service or sent for repair should undergo decontamination and a “Decontamination Certificate” completed to indicate the contamination status of the device and that the equipment is safe to handle (see appendix for “Medical Equipment Service / Repair Requisition - Decontamination Certificate” and “Medical Equipment Decontamination Flowchart”). The clinical engineering department will not accept

equipment for repair without the completed “Service Repair Requisition / Decontamination Certificate”. The infection control department should be informed of any proposed equipment procurement and should be a member of the evaluation group to review the decontamination and infection control guidelines of the device. The following classification of infection risk associated with the decontamination of medical devices is adopted:-

Risk	Application of Item	Recommendation
High	<ul style="list-style-type: none"> Items that penetrate skin or mucous membranes, or that enter sterile body sites 	Sterilisation
Intermediate	<ul style="list-style-type: none"> Items that have contact with mucous membranes or are contaminated with organisms that are easily transmitted. 	High Level Disinfection or Sterilisation
Low	<ul style="list-style-type: none"> Items used on intact skin 	Clean

Table 1. Infection Control Guidelines RICG 00004.

2.4 Value for Money (VFM)

Clinical Engineering will aim to achieve ‘value for money’ through well-planned, thorough and clear approaches to activities. The main benefits of promoting VFM principles through Clinical Engineering in the hospital are:

- Implement a formalised equipment replacement program (Health Strategy Action 93)
- Initiate a planned preventative maintenance program (Health Strategy Action 93)
- Standardisation of equipment where possible.
- Compatibility of biomedical technology throughout the hospital network

- Establishment of an equipment library.

3.0 Scope of Policy

This policy applies to the Mid Western Regional Hospitals of the HSE Western Area, Network 7.

4.0 Definitions /Abbreviations.

CENG	-	Clinical Engineering
HSE	-	Health Service Executive.
IMB	-	Irish Medicines Board
VAT	-	Value Added Tax
VFM	-	Value for Money

5.0 Procedures.

5.1 Equipment Request Procedure.

It is the responsibility of the Clinical Engineering department to advise the management team and clinical networks on the status of existing equipment for replacement and the requirements of new equipment for expansion / new services. Given that many requests are received for procurement of equipment each year and given that funding is limited, a "Case of Need" must be established by the clinical networks at the beginning of each year for their requirements of biomedical equipment.

This Case of Need is to be submitted to the Clinical Engineering Department for assessment and from there forwarded to the management team for consideration of approval with advice on the

priority of the various requests so that an informed decision on approval can be made or otherwise.

The following is the minimum information required in establishing a “Case of Need”: -

- ✓ Is the device a replacement or additional to existing equipment?
- ✓ Is the device termed obsolete or beyond economic repair?
- ✓ Is the device required for a new service or expansion of service?
- ✓ Is the device required as a result of Risk Management or safety standards?
- ✓ To indicate estimate cost of equipment (including VAT).
- ✓ Other relevant information.

5.2 Management Case of Need Approval.

Management will submit to the HSE a request for capital funding for procurement of the approved Case of Needs. In the event that the allocated capital funding is not sufficient, a reprioritisation of the requests is to be initiated by the network management team with the advice of the Clinical Engineering department.

The network management team would then indicate the final approved Case of Need to the Clinical Engineering department for initiation of the procurement process.

The approval from management is to indicate as a minimum the following information: -

- ✓ Device Description
- ✓ Quantity.
- ✓ Amount allocated for procurement.
- ✓ Time scale for completion of procurement e.g. year-end.
- ✓ Other relevant information.

5.3 Equipment Selection

Equipment specifications are to be drafted by the Clinical Engineering Department in conjunction with the clinical users. A user evaluation group incorporating the necessary clinical, technical and financial skill mix for each device that is tendered for is to be established. A criterion is to be drafted by the user group for the purpose of evaluation and scored according to the set criteria. An evaluation form must be completed for each item of equipment evaluated. The “Biomedical Equipment Evaluation Form” is appended to this policy.

Awarding of tender will be based on Clinical/User, Technical and Commercial assessment as per national procurement policy procedures.

The following criteria to apply to Equipment selection: -

- ✓ Drafting of Equipment Specifications.
- ✓ Establish a User Evaluation Group.
- ✓ Formulation of Evaluation Criteria.
- ✓ Infection Control membership of evaluation group.
- ✓ Completion of Biomedical Evaluation Form.
- ✓ Formulation of Life Cycle Cost Analysis.
- ✓ Adherence to National Procurement Policy Procedures.

5.4 Equipment Trials

It may be necessary to carry out equipment trials for the purpose of evaluation and selection. Equipment trials must be sanctioned via the Clinical Engineering Department to ensure that the equipment is safe for use in a clinical setting, is suitable for its intended purpose and is logged onto the equipment register to ensure traceability. An electrical safety test is to be performed on site by the supplier prior to installation for clinical use. Equipment trials should have a scheduled time scale and evaluated on the criteria as prepared by the user evaluation group. Such trials must be carried out on the supplier's indemnity.

Important: - Equipment must not be used on trial in the Hospital setting prior to acceptance test by the Clinical Engineering Department and Infection Control Department. An electrical safety check is to be performed on site by the supplier prior to use in a clinical setting. Cleaning and decontamination guidelines are to be approved by the infection control committee.

The following criteria to apply to Equipment Trials: -

- ✓ Electrical Safety Test.
- ✓ Cleaning and Decontamination guidelines acceptance.
- ✓ Supplier Proof of indemnity.
- ✓ Clinical Engineering Department acceptance procedure.
- ✓ Trial period.
- ✓ Evaluation criteria.

5.5 Gifts / Donations.

Equipment, which is leased, donated, hired or presented as a gift, must meet the requirements of the general conditions in this document. The Clinical Engineering department is to be informed prior to any proposed equipment procurement by charity groups, so as to facilitate advice on compatibility and standardisation of technology within the network.

It must undergo acceptance testing by the Clinical Engineering Department and be logged on to the Equipment Register.

The following criteria to be followed for Gifts / Donations: -

- ✓ Clinical Engineering Department informed.
- ✓ Infection Control Department Informed.
- ✓ Specification draft by Clinical Engineering Department and clinical users.
- ✓ Clinical Engineering Department equipment acceptance.
- ✓ Where possible standardisation of equipment.

5.6 Commissioning / Installation.

The Clinical Engineering Departments operate a computerised asset register and are in the process of introducing an equipment management system called MEDI-MISER by TISCOR. This facilitates the recording of equipment information such as location, owner, procurement details, maintenance schedules, breakdown records and general equipment history.

On availability of resources, maintaining this database is the responsibility of the Clinical Engineering Department who will update the information on a regular basis. Each item of equipment is given a unique registration number, called the Hospital Control (Asset) Number.

Therefore it is necessary for the Clinical Engineering Department in conjunction with the relevant unit department head to arrange commissioning and installation dates. On arrival, the Clinical Engineering department must perform equipment acceptance test and providing the equipment passes the test criteria and the manufactures performance test, the equipment will then be logged onto the Equipment Management System. All equipment must come complete with relevant calibration certificates, user manual, service manual, cleaning and decontamination guidelines.

On completion of equipment acceptance the clinical engineering department will issue a control (asset) number to the device.

The following criteria to be followed for Commissioning / Installation: -

- ✓ Clinical Engineering Department, Equipping Officer/Supplies Officer and relevant HOD to arrange installation date.
- ✓ Acceptance test procedure.
- ✓ Assignment of Hospital Equipment Control (Asset) Number (issued by Clinical Engineering).
- ✓ Electrical Safety Test Certificate.
- ✓ Calibration Certificates
- ✓ Cleaning and Decontamination Guidelines.
- ✓ User Manual.
- ✓ Service Manual.

5.7 User Training.

In line with the Risk Management initiative it is necessary to ensure that the relevant users are trained in the operation of the equipment. The Equipping Officer in conjunction with Clinical Engineering Department, to coordinate and ensure that there are adequate arrangements for training of relevant staff on new equipment. The department head of the unit to where the equipment is to be utilised must ensure that they are in receipt of the equipment user manual when accepting new equipment and to ensure that new or additional staff receive user training. All training courses are to be documented with records of attendees. All users have a professional responsibility to ensure that they are trained in the safe use of the equipment. The department head is to ensure that staff is aware of the infection control and decontamination guidelines for the equipment.

The following criteria to apply to User Training: -

- ✓ Documented user training to be provided by Supplier.
- ✓ New or additional staff to receive user training.
- ✓ HOD to ensure user manual is available in the department.
- ✓ Infection Control and Decontamination guidelines for equipment.
- ✓ Users to ensure competency in the use of the equipment.

5.8 Regional Tender.

Following network management funding approval for the various “Case of Need” requests, items should be identified that are best procured by regional tender so as to optimise purchasing power and to obtain best value for money.

For biomedical equipment to be procured via a regional tender it is a requirement to have clinical engineering representation on the regional user evaluation group to provide the technical evaluation of the equipment. A percentage of the award criteria are to be allocated for the clinical engineering technical evaluation. The responsibility for the provision of advice on the appropriate type and cost of maintenance contract pertaining to the proposed equipment procurement rests with the clinical engineering department, who following evaluation will advise as to whether the appropriate maintenance contract is to be provided in total by clinical engineering, shared between clinical engineering and supplier or to be provided in total by the supplier.

Equipment trials for regional tender that are to take place in a Hospital setting for the purpose of evaluation will require acceptance testing by clinical engineering to ensure that the equipment is safe for use in a clinical setting, is suitable for its intended purpose and is logged on the equipment register to ensure traceability. An electrical safety test is to be performed on site by the supplier prior to installation for clinical use and verified by clinical engineering. Equipment trials should have a scheduled time scale and evaluated on the criteria as prepared by the user evaluation group. Such trials must be carried out on the supplier’s indemnity.

Following award of tender the clinical engineering department in conjunction with the relevant unit department head are to arrange suitable commissioning and installation dates. On equipment arrival, the clinical engineering department must perform equipment acceptance test and providing the equipment passes the test criteria together with the manufactures performance test, the equipment will then be logged on the Equipment Management system. All equipment must come complete with relevant calibration certificates, user manual, service manual, cleaning and decontamination guidelines.

On completion of equipment acceptance the supplies officer will be advised to issue a GRN, this is to ensure that all items have been received and operating to manufactures specifications.

Important: - Equipment must not be used on trial in the Hospital setting prior to acceptance test by the Clinical Engineering Department and Infection Control Department. An electrical safety check is to be performed on site by the supplier prior to use in a clinical setting and verified by clinical engineering. Cleaning and decontamination guidelines are to be approved by the infection control committee.

The following criteria to apply to regional tenders: -

- ✓ Specification draft in conjunction with clinical users.
- ✓ Clinical Engineering representation on regional user group.
- ✓ Equipment trial acceptance test.
- ✓ Maintenance contract evaluation by clinical engineering.
- ✓ Arrange installation date in conjunction with relevant HOD.
- ✓ Perform acceptance testing.
- ✓ Assignment of Hospital Equipment Control (Asset) Number (issued by Clinical Engineering).
- ✓ Electrical Safety Test Certificate
- ✓ Cleaning and Decontamination guidelines acceptance.
- ✓ Calibration Certificates.
- ✓ User Manual.
- ✓ Service Manual.
- ✓ Goods Received Number (GRN) to be issued by equipping/supplies officer on approval of equipment acceptance.

5.9 Equipment Maintenance / Service Contracts.

Servicing arrangements of biomedical equipment within the network are provided either in-house by the clinical engineering department or on a shared basis with the relevant equipment suppliers. The responsibility for the provision and advice on such services rests with the clinical engineering department. It is the responsibility of the clinical engineering department to validate all service reports.

Within the clinical engineering department's computerised equipment management system, the department will maintain detailed service history information that includes information on items of equipment that necessitate external service contract with suppliers. This database will include the logging of spare parts used during servicing, for tractability and product liability purposes.

The following criteria to apply to Equipment Maintenance / Service Contracts: -

- ✓ Clinical Engineering Department to be centralised budget holder for all medical equipment service contracts.
- ✓ Responsibility of CENG for the management of external service contracts.
- ✓ CENG to provide recommendation on external service contract approval.
- ✓ Validation of service reports by CENG.
- ✓ CENG to maintain all service records.

- ✓ CENG to ensure servicing is performed in line with the manufacture's recommendations and procedures.

5.10 Equipment Malfunction.

In the event of a fault on biomedical equipment, the user must in the first instance inform the clinical engineering department. The user is to complete a Clinical Engineering "Repair / Service requisition" (requisition includes decontamination certificate), remove equipment from use and clearly label equipment as "Out of Service". A work order will be issued by the CENG to schedule the repair either by in-house personnel or by the appropriate external service provider if necessary. Under no circumstances should the user attempt to repair the equipment.

The following criteria to apply to Equipment Malfunction: -

- ✓ In the first instance the user to inform CENG of equipment malfunction.
- ✓ User to remove equipment from use and clearly label equipment as "out of service".
- ✓ User to complete "Repair/Service Requisition (Decontamination Certificate)"
- ✓ CENG to issue work order to schedule repair either in-house or externally.
- ✓ If scheduled repair is performed by external service provider the CENG to validate service repair report.
- ✓ CENG to maintain all repair records.
- ✓ CENG to ensure repair is performed in line with the manufacture's recommendations and procedures.

5.11 Unforeseen Case of Need.

Throughout each calendar year there will inevitably be unforeseen circumstances that may necessitate a request to management for the procurement of biomedical equipment. This may be due to various reasons such as new Consultant, equipment beyond economic repair, risk, safety and others. In this instance the "Case of Need" must still be compiled and submitted to CENG for evaluation. The case of need will be advised to management for approval consideration and to determine if and where funding can be sourced. If the "Case of Need" is approved, management are to indicate to CENG to initiate procurement process.

The following criteria to apply to Unforeseen Case of Need: -

- ✓ "Case of Need" to be submitted by user to CENG for evaluation.

- ✓ Management and Equipping Officer advised by CENG of “Case of Need”.
- ✓ Management to advise CENG and Equipping Officer of approval to proceed or otherwise.
- ✓ Equipping Officer/Supplies Officer or CENG to initiate procurement process if applicable.

5.12 Capital Development Projects and Minor Capital.

For capital projects where there is a requirement for biomedical equipment it is essential that the Clinical Engineering Department is incorporated as a team member in development projects and the planning of new services so as to facilitate in assisting in identifying biomedical equipment requirements. This will ensure that new technology is compatible with the existing environment, contributes to standardisation where applicable and contributes to facilitation of the linkage between primary care and secondary care.

For minor capital it is the responsibility of clinical engineering to have in place a planned replacement programme of equipment and to advise the management team and capital projects on the status of existing equipment for replacement and the requirements of new equipment for expansion / new services. Given that many requests are submitted for procurement of equipment each year from the various departments and given that funding is limited, clinical engineering will provide advice to management of the various “Case of Need” requests so that an informed decision can be formulated for consideration of submission for funding approval.

The Clinical Engineering Department will call upon a number of facilities available to them to enable the “Non Clinical Capital Network” to benefit from value for money and service with respect to biomedical equipment. Checks will be made to verify that equipment is supportable and that breakdown and maintenance cover is available. The manufacture or supplier will be required to demonstrate to the department that the equipment complies with the relevant safety requirements and standards.

The following criteria to apply to Capital Development Projects and minor capital: -

- ✓ CENG to be a member of the non-clinical capital project network.
- ✓ CENG to advise on compatibility and linkage of services.
- ✓ CENG to ensure VFM is realized for medical equipment for the project.
- ✓ CENG to ensure equipment complies with the relevant safety requirements and standards.

Appendix

Clinical Engineering No. **XXXX**
Repair/Service Requisition & Decontamination Cert

PART A

Print Your Name: Date:/...../.....

Department/Ward: Tel. Ext.

Equipment Type: **Asset/Serial No**

Give brief fault description:
.....
.....

B. Has the equipment been adequately cleaned prior to being disinfected? Yes No

Which of the following has been used to disinfect this equipment?

- 1. Alcowipe (Isopropyl Alcohol 70% v/v)
- 2. Neat Milton
- 3. Precept 1,000 ppm
- 4. Precept 10,000 ppm.
- 5. Nu – Cidex
- 6. Autoclaved

C. Has the equipment / accessories been suitably cleaned such that it is ready for use on another patient? Yes No

Where equipment / accessories cannot be cleaned / disinfected, it must be placed in a sealed clean plastic bag.

Medical Equipment Decontamination Flowchart



