Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Procedure for Equipment Decommissioning

Procedure No. 109

	Print Name	Title	Date
Prepared by	**Bernard Ryan**	**Principal Clinical Engineering Technician**	**23rd Sept 04**
Reviewed by	**Gerard O'Rourke**	**Equipping Officer**	**23rd Sept 04**
Corporate Authorisation	**J.G. MacNamara**	**T.S.O.**	**23rd Sept 04**

INTRODUCTION

The purpose of this procedure is to outline the procedures relating to the Commissioning and Decommissioning of Clinical Equipment.

Scope

This procedure applies to Clinical Equipment.

Responsibility

It is the responsibility of the Principal Clinical Engineering Technician in the Dept. of Clinical Engineering in conjunction with the Equipping Officer in the Project Office.

PROCEDURE

1 Identifying the Need and Responsibility

Prime Responsibility: Principal Clinical Engineering Technician & Equipping Officer

1. At the earliest indication that new clinical equipment is required, the Principal Clinical Engineering Technician or representative will take part in discussions or meetings with the Equipping Officer and Clinical Users, to determine the scope of operation for which the new equipment is intended.
2. A specification will be drafted for discussion, leading to an agreed specification for the equipment, and a list of potential suppliers.
3. From the agreed specification a tender specification will be drawn up by the Equipping Officer which will detail the general specification, technical specification, supplier's questionnaire, sections to evaluate the potential selection criteria and other details pertinent to the equipment and its intended use.
4. The tender will be distributed by the Equipping Officer to all potential suppliers and their replies will be evaluated against the agreed criteria.
5. From this point, discussion and equipment trials may take place to narrow the selection of equipment.
6. Once the equipment has been selected, the HSE Mid-Western Area's purchasing procedure (not within Clinical Engineering scope) is invoked. Notification of supply is requested from the supplier and notified to the Equipping Officer, who in turn will notify Clinical Engineering.
7. At this point the Principal Clinical Engineering Technician or representative will determine whether the equipment should be managed by Clinical Engineering or elsewhere within the Health Board.

2 Receiving New Equipment

Prime Responsibility: Equipping Officer & Principal Clinical Engineering Technician

1. New equipment is to be referred to the Clinical Engineering Dept. upon receipt by the Equipping Officer or representative. The Principal Clinical Eng. Tech. will check whether the equipment is to be maintained by Clinical Engineering or elsewhere within the Health Board.
2. The inspection required is limited to outer packaging. Section A of Form CE1 to be completed by the person receiving the equipment. Advise the Equipping Officer and the Principal Clinical Eng. Tech. if the outer packing is damaged beyond normal transit wear and tear. The severity and any equipment damage should be considered.
3. The Equipping Officer or representative assigned to the delivery will obtain the paperwork to the source of the equipment from the person who delivers it.

3 Commissioning New Equipment

Prime Responsibility: Principal Clinical Engineering Technician

1. For new equipment the Clinical Engineering Technician will carry out acceptance checks as detailed in Section B of Form CE1. This will include inspection of the equipment for any physical damage, checking for CE marking, and also marking indicating Class and Type of electrical protection. The technician will also check the mains plug and fuse and record the rating of both. This will be followed by an initial power up to ensure all controls lamps and indicators are working, and that nothing gives any cause for alarm, e.g. smells, odours, smoke, etc. A performance test in accordance with manufacturer's instructions should also be carried out before releasing the equipment. The Technician will also be responsible for insuring that all electro-medical equipment is electrically safety tested in accordance with the relevant EN 60601-1 or EN 61010-1 standard. Corrective action would be taken as necessary, depending on what is found during the tests. The above tests can be carried out by the Clinical Engineering Technician or by the suppliers Technician under the supervision of the Clinical Engineering Dept.
2. The Clinical Engineering Technician will also ensure that all documents are present for the equipment, including manuals etc.
3. After completion of all tests the technician will assign a Clinical Engineering Asset number to the equipment and complete the registration documentation. The equipment must now be entered onto the database and all documents passed to the Principal Clinical Engineering Technician.

4 Commissioning Trial or Loaned Equipment

Prime Responsibility: Principal Clinical Engineering Technician

1 On notification of equipment for trial or loan, the Clinical Engineering Dept. will ensure the supplier of the equipment signs an indemnity form (Form CE2) indicating the period of the trial or loan.

2 For trial or loaned equipment the supplier will be required to produce evidence that the equipment has been maintained in accordance with manufactures instructions. The supplier will also be required to carry out a full safety check, on site, in accordance with the relevant EN 60601-1 or EN 61010-1 standard on all electro-medical equipment.

3 The technician will also ensure that all documents are present for the equipment including manuals etc.

4 The equipment must now be entered on to the database and all documents passed to the Principal Clinical Engineering Technician.

5 Planned Maintenance Arrangements

Prime Responsibility: Principal Clinical Engineering Technician

1. Once equipment has been satisfactorily commissioned, the Principal Clinical Engineering Technician will evaluate the management of the maintenance requirements for the equipment.
2. This evaluation will be used in considering the current workload, expertise, and other resource requirements in determining whether an outside company should be used for repair and/or maintenance.
3. If there is more than one supplier of the equipment a tender will be drawn up and distributed to potential suppliers for their response. However, in the vast majority of cases the supplier of a particular product will also be the authorized service agent for the manufacturer of that product and as such would be the

only company to have direct technical support from the manufacturer to enable them to supply service support and spare parts.

4. An appropriate supplier will be selected and their details entered on the database if necessary along with the equipment they are to repair and/or maintain.

6 Obsolescence & Withdrawal of Support

Prime Responsibility: Principal Clinical Engineering Technician

1 Formal notification of obsolescence or withdrawal of support may not be received from the manufacturers.

2 Such notification that a certain type of equipment is no longer maintained, serviced, or spares are available may be notified during conversation with the supplier. Following such notification the Clinical Eng. Dept. will contact the supplier/manufacturer and request formal notification in writing from them.

3 When it is known that an item of equipment is obsolete or support has been withdrawn the Clinical Engineering Dept. will update the database for all those items.

4 The Principal Clinical Engineering Technician will check which equipment is at immediate risk due to the notice of obsolescence and take action according to the situation which could be to wait for the next planned maintenance visit or to immediately issue an advance notice of obsolescence.

5 If the equipment is still serviceable and fully and safely working then it will remain in service until a replacement has been obtained.

7 Decommissioning

Prime Responsibility: Principal Clinical Engineering Technician

Most equipment for decommissioning will have been identified through the planned process of replacement of obsolete equipment.

However, if during repair or planned maintenance the technician finds an item to be beyond economical repair, unsafe to use, etc. the item should be returned or retained in the service workshop. A defective equipment label must be attached.

The technician should make an assessment of the item of equipment and advise the Principal Clinical Eng. Tech.

The Data Base inventory should now be updated.

Where appropriate the equipment can be disassembled and serviceable parts can be salvaged.

Salvageable parts should be either labeled or bagged and labeled with reference to the machine, equipment or manufacturer they came from.

Unusable parts should be disposed of by notifying the porters to arrange collection. Care must be taken to do this following the HSE Mid-Western Area's waste disposal policy.

References: EN 60601-1 & EN 61010-1

Appendices : Form CE1 and Form CE2

Appendix 1:

Clinical Engineering Dept - MWRH
*Equipment Acceptance - Form CE **1***

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Acceptance Checks

Asset No Serial No Location

Job Ref

Date:...../...../..... Time taken Hrs/Mins:……/……

Equipment Description: …… Model: ……..

Manufacturer: …… Supplier: ……..

Acceptance check	**Comment**	**Pass**
Is the outer packing damaged beyond	If yes, reject the equipment. Contact	Yes / No

reasonable transit wear and tear?	both the Supplier and the User. Inform the Equipping Officer.	
Section B		
Is the equipment itself damaged in any way?	If yes, reject the equipment. Contact both the Supplier and the User. Inform the Equipping Officer.	Yes / No
Is the equipment CE marked?	If no, reject the equipment	Yes / No
If the equipment requires some degree of assembly such as casters, mounting brackets etc. are there suitable instructions supplied with the equipment on how to do this correctly?	If no, indicate in this box 'No instructions provided'.	Yes / No
Are there markings on the equipment indicating the: a) Class of electrical protection, 1 or 2? b) Type of electrical protection, B, BF, CF?		Yes / No
This equipment will need planned maintenance. Does a generic service template exist?		Yes / No
Does the equipment have a pre fitted 13 amp mains plug?	If No, State the amp rating of mains plug …… and the amp. rating of fuse fitted. ……	Yes / No
Has an instruction manual been supplied?	If no, obtain one prior to releasing the equipment	Yes/No
Has the equipment been tested for electrical safety?	To be carried out by Clinical Eng. Tech.	Yes/No
Does the equipment pass all of the above conditions?	If yes, release equipment to user. If no, give reasons below.	Yes / No

Can the equipment now be released for use? YES / NO Initials: Date:
Reasons if not:

Appendix 2:

Form CE 2

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

STANDARD FORM OF INDEMNITY

For equipment on loan from a supplier to the Health Service Executive

Mid-Western Regional Hospitals

AN AGREEMENT made the _____ day of _____200

BETWEEN Health Service Executive ("the Authority") and

_____ ("the Supplier").

WHEREAS

1. The Supplier is the owner of the equipment described in the Schedule ("the equipment").

2. The Supplier wishes the Authority to use the equipment for the benefit of the Supplier for the purpose of evaluation, testing, research, design, investigation or trial demonstration.

IT IS HEREBY AGREED that the Supplier shall lend and the Authority shall borrow and use free of charge the equipment for the period specified in the Schedule in the premises specified in the Schedule ("the premises") on the terms set out below.

1. The loan of the equipment shall be deemed to be a contract for the hire of goods as defined by section 38 of the Sale of Goods and Supply of Services Act, 1980.
2. The Supplier shall be liable for and shall indemnify the Authority against all liability in respect of personal injury to or the death of any person, loss of or damage to property and any loss or expense in consequence of or in any way arising out of the installation, presence, use or removal of the equipment on or from the premises provided that this indemnity shall not extend to liability resulting from the negligence of the Authority's own servants or agents.

3. (a) The Supplier shall insure against its fully liability under Condition 2.

(b) The Public Liability insurance cover shall be in the minimum sum of € 6.4 million in respect of any one incident, with a specific indemnity to the Authority. The insurance cover in relation to product liability shall be in the minimum sum of €6.4million.

(c) The Supplier upon request shall produce to the Authority documentary evidence that the insurance is properly maintained.

(d) Should the Supplier default in insuring the Authority may itself effect insurance and may charge the cost together with an administration charge of 5% to the Supplier.

4. The Supplier shall provide the Authority with written evidence on the safety of the equipment, drawing attention to any failures to comply with relevant IEC standards or aspects of safety that have not been tested. Restrictions on the use of the equipment necessary to ensure the safety of patients or staff shall be pointed out to the Authority.

5. A delivery note shall accompany the delivery of the equipment, identifying the equipment by serial number or otherwise.

6. Detailed instructions in the use of the equipment shall be given to the Authority's nominated staff by a qualified agent of the Supplier and detailed instruction manuals, where available, shall be supplied to the Authority.

7. The equipment will not be modified or interfered with by the Authority without the agreement of the Supplier.

8. The Authority shall not be liable for any charge for maintenance, repair, consumable materials and accessories required for the operation of the equipment during the period of the loan or for any carriage or installation charges except prior notification to and the issue of an official purchase order by the Authority.

9. (a) On receipt of a written request at any time from the Authority the Supplier shall remove the equipment from the premises with all practicable speed free of charge and at that time provide the Authority with a receipt for the equipment.

   (b) The Authority shall permit the supplier to remove the equipment from the premises on receipt of reasonable notice in writing.

   (c) The Supplier will be responsible for the cost of reinstating the premises, including the services therein, to the satisfaction of the Authority.

10. The equipment shall remain continuously at the Supplier's risk, during and after the period of the loan.

SIGNED on behalf of the Authority _____

SIGNED on behalf of the Supplier: _____

THE SCHEDULE

1. The Equipment

Manufacturer:

Description:

Model:

Serial No:

Value:

2. Period of Loan

_____ years _____ months commencing the _____ day of _____200

3. The Premises

Mid-Western Regional Hospitals

……

…….
on behalf of

..... Ward/Dept.

CE2 Standard Form of Indemnity

Dept. of Clinical Engineering
Mid-Western Regional Hospitals