Policy Compliance Procedure

Health
Hunter New England
Local Health District

Medical Equipment – Corrective Maintenance

Sites where PCP applies	All Sites within HNE Health
Target audience	All HSM, GM, DH, NUM and Equipment Officers
Description	Sets out responsibilities for implementing AS/NZS 3551:2012, AS/NZS 3200.1.0:1998, AS/NZS 2500: 2004 and AS/NZS 3003: 2011 including local procedures for the corrective maintenance of medical equipment

Go to Procedure

Keywords	Medical Equipment Corrective Maintenance
This PCP relates to NSW Ministry of Health Policy Directive	PD2018_013 Work Health and Safety: Better Practice Procedures
PCP number	PD2018_013:PCP 18
Replaces existing document?	No

Related Legislation, Australian Standard, NSW Ministry of Health Policy Directive or Guideline, National Safety and Quality Health Service Standard (NSQHSS) and/or other, HNE Health Document, Professional Guideline, Code of Practice or Ethics:

- Australian Standard AS/NZS 3551:2012 Management programs for medical devices
- AS_NZS_IEC_60601.1_2015 Medical electrical equipment - Part 1 General requirements for basic safety and essential performance
- Australian Standard AS/NZS 2500: 2004: Guide to safe use of electricity in patient care
- Australian Standard AS/NZS 3003: 2011: Electrical Installations Patient Areas
- ACHS EQuIPNational Accreditation Standard 15
- NSW Work Health and Safety Act 2011
- *Managing Electrical Risks in* the Workplace Code of Practice February 2016

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Summary

- To establish the procedure for corrective maintenance of medical equipment within HNE Health
- To clearly define the responsibilities of HNE Clinical staff , HNE Clinical Technology (HNECT) and service providers (manufacturer's , sponsors and contractors) with regards to corrective maintenance of medical equipment within HNE Health District

Risk statement

To ensure that Hunter New England Area Health complies with the requirements of the Australian Standards with regards to management of medical equipment and that corrective maintenance is performed to ensure all medical equipment are safe, available and function to manufacturer's specifications , at all times.

Risk Category:

Risk Category	Source of the risk	Element of Risk	Consequences
Clinical care and patient safety	Faulty medical equipment	Staff, patients, visitors	Injuries and death

BACKGROUND

Hunter New England Local Health District (HNE Health) will comply with practices for Purchasing, Inspection, repairing Testing and Labelling of Medical equipment as defined in the Australian Standard AS/NZS 3551:2012.

Hunter New England Clinical Technology (HNECT) Is the Medical Engineering Department established within HNE Health to manage compliance with this standard.

1. PURPOSE AND SCOPE

- To establish the procedure for performing corrective maintenance of medical equipment within HNE Health.
- To clearly define the frequency of testing and preventative maintenance of medical equipment.
- This procedure excludes Medical Imaging equipment

Note

Requirements for Medical Equipment must not be confused with those of General Electrical equipment (AS/NZ3760:2010) which have totally different applications and electrical safety requirements.

2. RESPONSIBILITIES

All Executive Directors, General Managers, Service Directors, Cluster Managers, Clinical Stream Managers, Clinicians and Department Managers with Medical Equipment within their unit are responsible for complying with this Policy.

3. DEFINITIONS

Acceptance Testing: A set of processes, which are performed before a newly acquired medical device may be released for clinical use. Acceptance Testing usually consists of an electrical safety and full functional test of the device. For equipment owned by HNE Health or on long term rental / loan (> 1 year), this also includes issuing a Medical Asset number to the device and entering it into the HNECT asset database.

Medical Equipment:

A medical equipment is

a. Any instrument, apparatus or appliance, including software, whether used alone or in combination, which makes physical or electrical contact with the patient, or transfers energy from or to the patient, or detects such energy transfer to or from the patient, and is intended to diagnose, treat or monitor the patient.

b. An accessory to such an instrument, apparatus, appliance, material or other article.

Corrective Maintenance

Maintenance carried out on a medical device, accessory or a system after fault recognition and intended to restore the device, accessory or a system into a state in which it can safely perform its function specified by the manufacturer.

Preventative Maintenance: This comprises of the scheduled maintenance work including but not limited to replacing components of a device susceptible to wear, fatigue and depletion, performing calibrations and verification of functions **prior** to failure.

Routine In-service Testing: This comprises of a series of electrical safety testing procedures and corresponding functional testing to verify the correct and safe operation of a piece of equipment.

Safety test label: this is an adhesive label indicating the date tested, next test date due and the technician who tested it. This is adhered to the equipment and/or the power cable.

Incident: An event involving medical devices and/or equipment resulting in or having the potential to result in unexpected or unwanted outcomes that affect the safety of patients, staff or other people.

4 PROCEDURE

4.1 General principles for use of any Medical equipment

Prior to use on patient the operator (user) must ensure

- Performing necessary checks recommended by the manufacturer to ascertain the correct operation of the medical equipment.
- Inspecting the equipment housing for visible cracks and checking the power cord for exposed conductors/wires
- Confirming the currency of periodic safety test label on the equipment. It is the responsibility of the operator (user) to ensure their equipment is within the date for inspection and testing, if they intend using it on patients

4.2 Reporting of the faulty equipment

- Any Medical equipment found to be faulty or damaged shall be isolated and labelled with a HNECT Fault Tag (see Appendix 1, Figure 1) in compliance with AS/NZS3551-2012.
- This equipment shall be removed from service and reported to HNECT as soon as practically possible via telephone, email or in-person through sending it to the respective workshop.

4.3 After- hours support

- Currently John Hunter is the only hospital where HNECT offers an on-call service to provide after-hour support to critical medical equipment failures.
- This service can only be availed through the approval of the after-hour duty Nurse Manager and is charged to the respective cost centre in accordance with the current service level agreement(SLA) signed between the hospital and HNECT.
- Faulty medical equipment from other hospitals shall be sent to the respective HNECT workshop for repairs or where necessary, HNECT techs will attend to the fault on-site within business hours.

4.4 Maintenance strategies for medical devices

The corrective maintenance services for medical equipment in HNE district are either managed in-house through HNECT resources or outsourced to service providers through service agreements. The decision for choosing either strategy is based on factors such as clinical requirements, current HNECT capacity and geographical dispersion of devices as well as device associated risk factors.

4.5 Medical Equipment Maintained through HNECT

All corrective maintenance activities including fault finding, repairing, testing and tagging are carried out by HNECT staff on-site or in the workshops at John Hunter and Tamworth hospitals. All corrective maintenance records are updated to equipment database by the technical officer performing the corrective maintenance.

4.6 Medical equipment maintained under service agreements

Currently there are two major categories of service agreements across HNE local district in terms of responsibility for managing the maintenance activities involving medical devices covered by the agreements. These agreements managed by clinical users and agreements managed by HNECT. The corrective maintenance activities for equipment covered under corresponding service agreement are managed as under

a. User Managed Service Agreements

- Clinical users organise service calls with the respective providers in accordance with the service agreement terms and conditions
- Clinical users are responsible for approving and signing off the services provided by the provider
- Upon completion of the service activity , the provider shall send the respective clinical user a service report with complete details of the work done
- Clinical users maintain the service record/history of the medical equipment under contract
- It is advised that clinical users provide service reports received from vendors to HNECT so that the equipment history is updated on the HNECT central database.

b. HNECT Managed Service Agreements

- Clinical users report the faulty equipment under service agreement to HNECT as soon as practically feasible
- If the faulty medical device is covered under a fully comprehensive service agreement, HNECT will contact the service provider as soon as practically possible or as per the response time stipulated in the SLA with the respective hospital
- The provider will attend the faulty equipment as per the terms and conditions of the service agreement.
- If the faulty equipment is covered under a “Shared Support Arrangement” between the HNECT and the provider, HNECT shall attend to the call and provide frontline service and attempt to resolve the issue
- If the fault cannot be rectified by HNECT staff, it shall be escalated to the provider
- The provider will attend to the call as per terms and conditions of the service agreement.
- Upon completion of the service activity , the provider shall send a service report with complete details of the work done

4.7 Equipment involved in an incident

- All medical equipment involved in incidents shall be reported to the HNECT as soon as practically possible.
- An IIMS report ID shall be provided to HNECT to assist with the investigation process, if required.
- Remove faulty equipment or supplies and isolate them without altering the fault conditions such as operational and clinical settings that were in place at the time of the incident.
- Send the faulty device along with all accessories including power cord and patient leads etc. to the respective HNECT workshop as soon as possible.
- Upon receiving, HNECT will assess the faulty equipment, download memory logs where possible and if requested (by HNE quality and patient safety) contribute to the incident investigation process.
- Where it is considered that the medical equipment or medical electrical system did, or may have, contributed to an adverse event, details of the medical equipment and the event shall be reported to the equipment sponsor as well as to TGA.
- Any incidents resulting from equipment failures and involving patients or staff shall be put into IIMS Clinical and all ‘reportable incidents’ shall be reported to CE and SafeWork

NSW following the guidelines provided in PCP: Notification of Notifiable Incidents to CE and SafeWork NSW.

- Such equipment shall not be released for clinical use until the faults have been rectified and the equipment is tested and certified to manufacturer's specifications. In case of a 'reportable incident' approval from HNE patient safety and quality shall be sought before releasing the equipment for use.

4.8 Dispatching equipment to HNECT workshop

- All malfunctioning medical equipment should be reported to HNECT and sent to the respective workshop for repair.
- Where possible malfunctioning medical equipment should be sent to the workshop with accessories and consumable for the purpose of effective troubleshooting and fault finding.
- **All medical equipment, accessories and consumables must be decontaminated prior to making them available for repairs on site or dispatching them to the HNECT workshop**.
- All faulty medical equipment must be affixed with a HNECT Fault Tag (see Appendix 1, Figure 1) in compliance with AS/NZS3551-2012
- All details on the HNECT fault tag must be completed and signed by the staff dispatching the device to the workshop.
- HNECT may NOT accept medical equipment sent for repairs without or an incomplete fault tag.

4.9 Corrective maintenance of Medical Equipment

a. Equipment maintained in-house by HNECT

- All medical equipment received at HNECT workshop shall be triaged by the triaging officer or admin staff making sure the equipment is accompanied by a completed fault tag.
- A work request (Appendix 2, figure2) shall be generated using the Asset Tag (BME #) of the device in the HNECT computerised maintenance management system (EMS).
- Technical officers get their jobs assigned through EMS. However the respective Senior Technical Officers (STO) cam also review the jobs request, priorities and assign them to team members
- The technical officers shall repair the faulty equipment and test them for function as per manufacturer's specifications.
- An Electrical safety test per AS 3551-2012 will be performed if deemed necessary
- Preventive maintenance (PM) will be performed if the next PM is due within a reasonable timeframe of the repair. The PM schedule will be updated accordingly
- If necessary, equipment test and tags labels (appendix 4) shall be updated before releasing for clinical use.
- Equipment history records shall be updated in the HNECT database and equipment folder
- A completed service report/service request form (appendix 2, Figure 2) shall be sent along with the repaired device to the staff who requested the service

b. Equipment maintained under service agreement, warranty, Trial/loan

- The equipment under fully comprehensive service agreement or warranty shall be triaged in the same manner as in-house managed equipment.
- The technical officer for the respective area will contact the service provider and arrange repairs on-site or dispatch the equipment for repairing at contractor's premises as per the service agreement or warranty terms and conditions.

- Upon completion of the repair the contractor will return the equipment to HNECT workshop along with a detailed service report.
- The technical officer dealing with the contractor on the particular repair shall make sure the equipment is labelled and tagged appropriately and all clinical configurations have been reverted to the appropriate state.
- The technical officer shall update the equipment history in EMS as well as in the equipment folder.

c. Patient owned medical equipment

- HNECT does NOT perform corrective maintenance on patient owned medical equipment.

4.10 Returning of Repaired Medical equipment

- At John Hunter and Tamworth hospitals, the clinical department/porterage shall be informed of the completion of repairs and requested to collect the equipment.
- For other hospitals the technical officer repairing the device will dispatch it to the customer through an appropriate delivery service.
- A dispatch tag (Appendix 3, figure 3) shall be attached to each device being dispatched from the HNECT workshop to make sure the device reaches the desired destination.

4.11 Equipment Beyond Repairable Condition

- Any equipment that is rendered unrepairable by HNECT shall be discarded and the user shall be informed of the same through a disposal notice with a justification.
- All discarded equipment shall be marked in equipment database, removed from its clinical location and from the test and tag schedules.

4.12 Record keeping

- All records pertaining to corrective maintenance of the equipment shall be electronically archived equipment database
- The numerical results of the safety and functional tests are retained on HNECT asset database in the Clinical/Medical Engineering Department. Test results will be supplied on request.
- A completed service report/service (appendix 2, Figure 2) request form shall be sent along with the repaired device to the staff who logged the service request.

4.13 Compliance, Implementation and Monitoring

Compliance with this policy is mandatory for all Departments within Hunter New England Area Health and all staff within their divisions as specified in the document's scope.

Compliance with this policy is also mandatory for Hunter New England Clinical Technology Service (HNECT)

In the interest of workplace health and safety/duty of care to the employee, line managers/supervisors need to be aware of the employee’s level of competence and compliance with this policy.

It is the responsibility of the employee to communicate with their line manager/ supervisors in the event they see themselves unqualified to safely use the medical equipment in their area of responsibility.

Implementation plan will include but not limited to staff’s orientation, staff’s education and participation in annual mandatory education, medical equipment testing plans, and accreditation and ongoing in-service by the educators.

Compliance to the policy shall be monitored against the key performance indicators stipulated in the service level agreements

4.14 Feedback

Any feedback on this document should be sent to the Contact Officer listed on the front page.

5. REFERENCES

- Australian Standard AS/NZS 3551.2012: Technical Management Programs for Medical Devices
- Australian Standard AS/NZS 3200.1.0:1998: Approval and test specification-Medical electrical equipment
- Australian Standard AS/NZS 2500: 2004: Guide to safe use of electricity in patient care Safe Operating Procedures (SOP) for Medical Equipment
- Australian Standard AS/NZS 3003: 2011: Electrical installations - Patient areas
- ACHS EQuIPNational Accreditation Standard 15
- NSW Work Health and Safety Act 2011
- *Managing Electrical Risks in* the Workplace Code of Practice February 2016
  Notification of Notifiable Incidents to CE and SafeWork NSW. PD2013_050: PCP 12 and HNELHD Pol 13_09: PCP 1.

Appendix 1

HUNTER NEW ENGLAND CLINICAL TECHNOLOGY

John Hunter Hospital Workshop 0249213147, Tamworth Hospital Workshop 0267678023

FAULT TAG

Please fill in this form and attach it securely to your equipment before sending it to BME for repair. PLEASE PRINT CLEARLY

Equipment_____ BME No _____
Ward/Department_____Hospital_____
Contact Person_____Phone_____
Date_____Time _____

Please describe the fault or service required

_____
_____
_____
_____
_____

IIMS Incident ID (if applicable)_____

Accessories - Yes ☐ No ☐
List accessories
1. _____
2._____
3. _____

Please state if the equipment and accessories have been decontaminated prior to sending for servicing. Yes ☐ No ☐

Name _____ Signature_____

HNECT-FT V1.0

Figure 1 Fault Tag

Appendix 2

HUNTER NEW ENGLAND CLINICAL TECHNOLOGY

John Hunter Hospital Workshop 0249213147, Tamworth Hospital Workshop 0267678023

Service Request Form/Service Report

Service Request #_____

EQUIPMENT DETAILS

Description _____ Manufacturer _____

BME#_____ Serial # _____ Category ☐

Model_____ Installed Date _____SW Version_____

Location_____ Hospital _____

PM due Date _____ Battery due date _____

Repair Status (Please check)

Complete ☐ In Progress ☐ Pending ☐ Reason _____

Fault description

_____

_____

_____

Accessories 1. _____ 2._____

Date _____Time_____

Reporting Person _____ Phone_____

Work Performed

_____

_____

_____

Material Used

1. _____
2. _____

Preventive actions	Yes/No	Remark
Safety Test		
PM		
Battery Replacement		
Update Schedules		

HNECT officer

Name _____ Contact#_____

Date_____Time _____

N.B. Attach the service request form to the equipment when returning

HNECT-SR V1.0

Figure 2 Service Request

Appendix 3

HUNTER NEW ENGLAND CLINICAL TECHNOLOGY

John Hunter Hospital Workshop 0249213147, Tamworth Hospital Workshop 0267678023

Dispatch Tag

Request #_____

Equipment details

BME#_____ Serial # _____
Equipment Description _____ Manufacturer _____
Location_____ Hospital _____
Accessories 1. _____ 2._____

Customer

Name _____ Contact _____

Location_____ Department_____

Hospital_____

HNECT Officer

Name _____ Contact _____
Location _____ Hospital_____
Dispatch Mode _____Reference#_____
Date dispatched_____Time _____

N.B. Attach the service request form to the equipment when returning

HNECT-DT V1.0

Figure 3 Dispatch Tag

Appendix 4

Figure 4: HNECT Service and Test Tag

Figure 5: HNECT Trial / Loan Test Tag

Figure 6: HNECT AC Mains Cable Test Tag

HNECT Test Tags