Effective: 14 August 2020

Management of Medical Equipment Policy

1. Background

In accordance with MP 0110/19 Management of Medical Equipment Policy, under the Infrastructure Policy Framework, this Policy communicates how WA Country Health Service (WACHS) will manage owned, contracted and leased Medical Equipment over its lifecycle in accordance with the Australian and New Zealand Standard 3551:2012 – Management Programs for Medical Equipment.

The planning and availability of the right amount and type of well-maintained Medical Equipment is critical to ensure the delivery of safe patient care across WACHS.

2. Policy Statement

The purpose of this policy is to describe the processes required to manage Medical Equipment and address service delivery objectives and minimise the risk of serious incidents or harm to patients.

To effectively manage Medical Equipment the following must be adhered to:

Governance

The management of Medical Equipment involves asset operation and maintenance, replacement planning and procurement. Each Regional Office is responsible from an operational level to ensure that Medical Equipment is managed effectively and must report to the WACHS Medical Equipment Committee when required.

The WACHS Medical Equipment Committee has oversight of and decision-making responsibilities for the management of Medical Equipment from an organisational perspective. The Medical Equipment Committee ensures that the Medical Equipment information is readily accessible to individuals who are accountable for the management, use and maintenance of the Medical Equipment.

The Medical Equipment Committee provides advice to the Department of Health (DoH) Strategic Asset Planning Steering Committee via the WACHS Infrastructure Unit as required. The Committee is required to provide the DoH Infrastructure Unit with:

- a copy of the WACHS database by the last business day of March each year;
 and
- an endorsed Medical Equipment Management Report by the last business day of August each year.

Planning for equipment replacement

Each Regional Office is responsible for undertaking Medical Equipment replacement planning. Planning to replace or acquire new Medical Equipment must be in accordance with the short-term (two years), medium term (five years) and long term priorities (10 years) as outlined in the WACHS Strategic Asset Plan (SAP) 2019-2029.

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In accordance with the SAP, each Regional Office must maintain their five year Medical Equipment Replacement Plan on the provided template that is issued with the annual request. Regional Directors are responsible for endorsing the plan and ensuring it aligns with the current clinical service framework to support safe and quality clinical care. Mitigation plans must be in place for any items identified as high risk.

Each Regional Office five year Medical Equipment Replacement Plan is to be submitted by the last business day of May each year to the WACHS Medical Equipment Committee to enable forecasting of funding requirements, procurement planning and identification of potential aggregation opportunities.

Suggested equipment lives are available on the WACHS Asset Management System and are provided from the international Global Medical Device Nomenclature (GMDN) system. These recommendations should be considered a baseline and may need to be adjusted dependant on factors such as wear and tear, service history and reliability, emerging technology, end of support notifications by manufacturers and frequency of usage.

Acquisition processes

Medical Equipment acquisition processes must be undertaken is accordance with the WACHS <u>Medical Equipment Procurement Policy</u>. Section 3.3 of the MP 0110/19 Management of Medical Equipment Policy describes the process of acquisition required to be adhered to by Health Service Providers. This includes:

- procuring Medical Equipment in accordance with requirements set out within the Procurement Policy Framework; and
- conducting acceptance testing and commissioning of Medical Equipment in accordance with the Australian and New Zealand Standard 3551:2012
 - Management Programs for Medical Equipment

Record and maintain asset information

The WACHS Asset Management system provides a single database for Medical Equipment across WACHS. The following asset information is to be recorded:

- All equipment assets under the control of WACHS
- A unique identifier for each asset
- The purchase cost
- Maintenance cycle
- Frequency of use
- A summary of any clinical incidents that occurred when using the Medical Equipment
- An estimate of the useful economic life of the Medical Equipment
- The responsible officer and/or the Regional Office accountable for the equipment and its location.

Biomedical Engineering (BME) performs routine and breakdown maintenance services to a large inventory of WACHS equipment through Electromedical and X-ray divisions. Each Regional Office is responsible for recording Medical Equipment asset data and service history in the WACHS Asset Management system. This is specifically for non BME maintained items such as patient care equipment.

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For WACHS BME serviced items the BME database 'E-Med' transfers asset data across to the WACHS Asset Management system on a daily basis.

The Fixed Asset Register (FAR) records the procurement information of all Medical Equipment assets valued greater than \$5,000.

Operate, maintain and monitor equipment

Section 3.5 of MP 0110/19 *Management of Medical Equipment Policy* requires each Regional Office to:

- Conduct a physical stocktake of Medical Equipment every two years to ensure that the Medical Equipment information in the database aligns with the Medical Equipment that is physically on site.
- Maintain Medical Equipment in accordance with the Australian and New Zealand Standard 3551:2012 – Management Programs for Medical Equipment. Regional Offices must have maintenance programs for Medical Equipment in place and regularly review the performance of Medical Equipment against these maintenance programs.
- Undertake performance verification activities on Medical Equipment in accordance with the *Australian and New Zealand Standard 3551:2012 Management Programs for Medical Equipment*.
- Review the utilisation of Medical Equipment to ensure that assets are being effectively used and notify the WACHS Medical Equipment Committee of Medical Equipment that is surplus to requirements.
- Conduct risk assessments of Medical Equipment failure and service interruptions. This will be in accordance with the WA Health Risk Management Policy to determine if the Regional Office Medical Equipment is identified as posing a potential risk to service delivery. The assessment must include any mitigation strategies that are being implemented to manage these risks.

Maintenance is to be undertaken as guided by the manufacturers recommendations to ensure Equipment remains in good condition, is used to full capacity, and its expected life is maximised. WACHS Medical Equipment is maintained by one of the following options:

- 1. BME
 - a. Fully serviced items
 - b. Minor role captured information; for replacement data and asset tracking only and record of minor maintenance such as an electrical safety check
- 2. Service contract
 - a. Regional Office/ site contract
 - b. WACHS wide contract
- 3. No service contract
 - a. Maintained by users/site
 - b. Breakdowns only

Regional Offices must provide clarification if an Equipment owner is unsure of maintenance service responsibility.

Decommission and disposal of equipment

Section 3.6 of MP 0110/19 *Management of Medical Equipment Policy* requires each Regional Office to ensure that Medical Equipment is decommissioned and disposed of when it reaches the end of its useful economic life in accordance with the WA Health Financial Management Manual.

An assessment must be performed by the Regional Office as part of the asset planning process to consider an asset's obsolescence, number of like assets available, availability of spare parts and the manufacturer's recommended useful life before the Medical Equipment is physically disposed of in accordance with the relevant aspects of the WA Health Financial Management Manual.

Any reports of missing or unable to locate equipment that are identified by clinical areas or listed on service or stocktake reports must be investigated and where necessary disposal action taken.

Equipment that has been replaced or becomes surplus due to changes in service delivery must be disposed. The Health Financial Management Manual Section 734 *Transfer and disposal of fixed assets* describes the processes to be followed. The following options must be considered:

- 1. Trade in
- 2. Sale
- 3. Transfer to another site
- 4. Retention by BME for spare parts or loan stock
- 5. Retention by site for back up
- 6. Disposal as waste material.

3. Definitions

Medical Equipment / Equipment

Any instrument, apparatus or appliance, including software, whether used alone or in combination, together with any accessories necessary for correct operation, that makes physical or electrical contact with the patient, or transfers energy to or from the patient, or detects such energy transfer to or from the patient, or is intended to diagnose, treat or monitor a patient.

Note: Items of equipment that were not originally designed as Medical Equipment, but which are supplied as part of, or interfaced with, other Medical Equipment, are considered to be themselves as part of a medical electrical system, and subject to the requirements of this policy. For further information on the types of medical devices and their classification, please refer to Section 41DB of the *Therapeutic Goods Regulations 2002*.

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4. Roles and Responsibilities

Chief Operations Officer

- From an organisational perspective oversees the Medical Equipment
 Committee to ensure oversight of and decision-making responsibilities for the
 management of Medical Equipment.
- Ensures compliance with MP 0110/19 *Management of Medical Equipment Policy*.
- Ensures a copy of the WACHS database and a completed Medical Equipment Management Report is provided to the DoH Infrastructure Unit annually.

Infrastructure

Infrastructure Unit

- Maintains WACHS Asset Management System database.
- Reports to the Medical Equipment Committee database information regarding performance, condition and missing items of Medical Equipment.
- Provides to Medical Equipment Committee a copy of the WACHS database and Medical Equipment Management Report Template for reporting to DoH Infrastructure Unit.

Biomedical Engineering (BME)

- Ensure that Medical Equipment information is recorded and maintained in the E-Med database.
- Repair and preventative maintenance of Electro medical and X-Ray equipment.
- Provides equipment service reports to sites, including notifications of obsolete equipment

<u>Procurement and Contract Management Directorate</u>

- Undertakes procurement of Medical Equipment Replacement Program funded Medical Equipment.
- Assists in procurement of other Medical Equipment

Regional Offices:

Regional Directors

- From an operational level are responsible to ensure that Medical Equipment is managed effectively.
- Ensure the Regional Office five year Medical Equipment replacement plan is maintained and provided annually to the Medical Equipment Committee.
- Ensure Medical Equipment and service contract procurement processes undertaken by the Regional Office are in accordance with policy requirements.
- Ensure that disposal of Medical Equipment is conducted in accordance with the Financial Management Manual.

Regional Finance Managers

 Ensure that accounting requirements for asset addition, transfer or disposal are undertaken in accordance with policy.

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Regional Facilities Managers

- Ensure that Medical Equipment information is recorded and maintained in the Asset Management System database.
- Ensures Medical Equipment is serviced appropriately.
- Ensure a physical stocktake review of Medical Equipment is conducted every two years to ensure that the Medical Equipment information in the database aligns with the Medical Equipment that is physically on site.

Senior Nurse at site

- Identifies Medical Equipment for replacement to enable completion of Regional Office five year Medical Equipment Replacement Plan.
- Participates in procurement and contract management activities for Medical Equipment.
- Ensures new asset information is recorded in the WACHS Asset Management System, and that obsolete assets are removed from the system.
- Ensures all Medical Equipment within their area is appropriately maintained and fit for purpose.

Clinical Staff

- Have received appropriate training in the safe use of the Medical Equipment.
- Operate Medical Equipment in accordance with manufacturer's instructions for use.
- Ensures faulty Medical Equipment is reported and sent for repair.
- Identifies and reports any risks related to Medical Equipment to the Senior Nurse at site.

5. Compliance

This policy summarises the mandatory requirements to comply with the WA Health MP 0110/19 Management of Medical Equipment Policy.

All medical equipment must comply with the Therapeutic Goods Regulations 2002.

Compliance with this policy is monitored through the reporting cycle undertaken by the Regional Offices, risk assessments and bi-annual physical stocktakes.

Failure to comply with this policy may constitute a breach of the WA Health Code of Conduct (Code). The Code is part of the <u>Integrity Policy Framework</u> issued pursuant to section 26 of the <u>Health Services Act 2016</u> (WA) and is binding on all WACHS staff which for this purpose includes trainees, students, volunteers, researchers, contractors for service (including all visiting health professionals and agency staff) and persons delivering training or education within WACHS.

The Chief Operations Officer ensures compliance with the MP 0110/19 Management of Medical Equipment Policy and reminds WACHS Employees that compliance with all policies is mandatory.

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6. Records Management

All WACHS corporate records must be stored in the approved Electronic Documents and Records Management System.

Records Management Policy

7. Evaluation

Evaluation of this policy is to be carried out by the WACHS Medical Equipment Committee.

8. Standards

National Safety and Quality Health Service Standards – 1.1, 1.29 Australian and New Zealand Standard 3551:2012 – Management Programs for Medical Equipment.

9. Related Policy Documents

WACHS Strategic Asset Plan 2019-2029

WACHS Medical Equipment Procurement policy

WACHS Biomedical Engineering testing and tagging of cords

WACHS Medical Equipment Committee Terms of Reference

10. Related WA Health System Policies

MP 0110/19 <u>Management of Medical Equipment Policy</u>
WA Health Financial Management Manual section 734 <u>Transfer and disposal of fixed assets</u>

11. Policy Framework

Infrastructure (Asset management)

This document can be made available in alternative formats on request for a person with a disability

Contact:	Clinical Procurement Manager (R. West)		
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