

Policy Frameworks

MP 0110/19 Effective from: 24 June 2019

Management of Medical Equipment Policy

1. Purpose

The Management of Medical Equipment Policy communicates how health service providers (HSPs) must 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. This policy enables HSPs to manage their medical equipment and address their service delivery objectives.

This policy supports the broader mandate by the State Government to strengthen links between asset planning and business decisions and is consistent with the Department of Treasury's *Strategic Asset Management Framework*.

This policy is a mandatory requirement under the *Infrastructure (Asset Management) Policy Framework* pursuant to sections 27(1), 34(2)(c) and 34(2)(j) of the *Health Services Act 2016.*

2. Applicability

This policy is applicable to all HSPs.

3. Policy Requirements

HSPs must meet the following requirements:

3.1 Governance structure for the management of medical equipment

- Establish and maintain an internal governance committee for the effective management of their medical equipment. The committee must be led by an executive sponsor and include members with decision-making responsibilities relevant for the management of medical equipment.
- When relevant, Department of Health representatives will attend HSP governance committee meetings and will report to the Department of Health's Strategic Asset Planning Steering Committee where necessary.

The Medical Equipment Management Working Group (MEMWG), consisting of representatives from all HSPs and the Department of Health, provides oversight of the management of medical equipment in accordance with this policy. The MEMWG will meet twice a year, with any additional meetings to be determined by the Chair. Refer to the *MEMWG Terms of Reference* for more details.

3.2 Plan to replace or acquire new equipment

• Plan to replace or acquire new medical equipment in accordance with the short-term (2 years), medium-term (5 years) and long-term (10 years) priorities as outlined in the HSPs' Strategic Asset Plans (SAPs). Alternatives to purchasing, such as contracting services or leasing equipment, must also be considered. Refer to the *Medical Equipment and Imaging Replacement Program Policy* and the *Asset Management Strategic Asset Plan Policy*.

3.3 Acquire equipment

- Procure medical equipment in accordance with requirements set out within the *Procurement Policy Framework*.
- Conduct acceptance testing and commissioning of medical equipment in accordance with the Australian and New Zealand Standard 3551:2012 Management Programs for Medical Equipment.

3.4 Record and maintain asset information

- Where equipment assets are owned or under the control of the HSP and have a purchase price of \$5,000 (excluding GST) or greater and a useful life of 2 years or more, record and maintain asset information that includes:
 - a. a unique identifier for each asset
 - b. status (owned, leased, loaned, contracted or donated)
 - c. type (new, replaced or refurbished)
 - d. the purchase cost (if donated, the market value)
 - e. useful life
 - f. maintenance cycle
 - g. a summary of any clinical incidents that occurred when using the medical equipment
 - h. the responsible officer or business unit accountable for the equipment and its location.
- All equipment with a value less than \$5,000 must be recorded in a separate list for insurance and maintenance purposes.

The medical equipment information must be readily accessible to individuals who are accountable for the control, use, maintenance and management of the medical equipment. Adequate controls must be in place to prevent unauthorised access or modifications to medical equipment records.

3.5 Operate, maintain and monitor equipment

- Conduct a physical stocktake review of medical equipment with a value of \$5,000 or more (excluding GST) in accordance with the Department of Health's stocktake policy. Refer to the *Financial Management Manual (*FMM).
- Maintain and undertake performance verification activities for medical equipment in accordance with the Australian and New Zealand Standard 3551:2012 – Management Programs for Medical Equipment (AS/NZS 3551:2012). HSPs must have maintenance programs for medical equipment in place and review the performance of medical equipment against these maintenance programs on a regular basis.

- When appropriate, review the utilisation of medical equipment to ensure that assets are being effectively used and notify the governance committee of medical equipment that is surplus to requirements. Surplus equipment must be decommissioned in accordance with the FMM.
- Conduct risk assessments in accordance with MP 0006/16 Risk Management Policy and local HSP policy guidance to determine if a HSP's 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. Extreme risk items must be reported to the Department of Health, together with the relevant reason on why this has not been replaced.
- Refurbished medical equipment must meet the same regulatory requirements of safety, quality and performance as applied to the original medical device.

3.6 Decommissioning and disposal of equipment

- Decommission and dispose of medical equipment when it reaches the end of its useful life and can no longer be used, in accordance with the FMM, *Therapeutic Goods Act 1989* (TGA Act) and *AS/NZS 3551:2012*. An assessment must be performed 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.
- In addition to the FMM list of appropriate disposal options, and where deemed safe and appropriate, HSPs can retain medical equipment for spare parts. HSPs must assess storage costs to decide if the solution is economical. To minimise the risk of adverse health outcomes, the decommissioned medical equipment must not be kept as backup and must be removed from the asset register.

4. Compliance Monitoring

HSPs, via their internal governance committee, are required to ensure compliance with the policy.

The Department of Health's role includes overall oversight, reporting to the Government and providing support to HSPs.

The Major Health Projects and Infrastructure team at the Department of Health, on behalf of the System Manager, will request HSPs to provide recorded asset information in accordance with this policy.

5. Related Documents

The following documents are mandatory pursuant to this Policy:

<u>MEMWG Terms of Reference</u>

6. Supporting Information

The following information is not mandatory but informs and/or supports the implementation of this Policy:

• N/A

7. Definitions

The following definition(s) are relevant to this Policy.

| Term | Definition | | | |
|--|---|--|--|--|
| Assets | For the purpose of this policy, assets are defined as items with a purchase price of \$5,000 (excluding GST) or greater, and a useful life of two years or more. | | | |
| Frequency of use | The number of times medical equipment is used, e.g. daily, weekly, bi-weekly, monthly, bi-monthly, yearly. | | | |
| Health Service Provider | Health Service Provider means a Health Service Provider established under section 32 of the <i>Health</i> <i>Services Act 2016</i> and may include North Metropolitan Health Service (NMHS), South Metropolitan Health Service (SMHS), Child and Adolescent Health Service (CAHS), WA Country Health Service (WACHS), East Metropolitan Health Service (EMHS), PathWest, Quadriplegic Centre and Health Support Services (HSS). | | | |
| Management of Medical Equipment Working Group | The Working Group comprises Health Service Provider and the Department of Health representatives. The Working Group makes decisions on matters relating to the management of medical equipment at Health Service Provider level. The Working Group is accountable and provides advice to the Strategic Asset Planning Steering Committee and assists in the implementation of medical equipment policy and practice, providing advice and direction on issues relating to the management of medical equipment. | | | |
| Medical 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 <i>Therapeutic</i> <i>Goods Regulations 2002.</i> | | | |
| Refurbished medical equipment | Reconditioning medical devices for safety and effectiveness with no significant change in their performance, safety specifications or service procedures as defined by the manufacturer and their original intended use. | | | |

| Strategic Asset Plan (SAP) | The SAP outlines the Health Service Provider's proposed service objectives; demand drivers and projections; and investment intentions for the next ten years. The SAP culminates in a summary of the asset proposals that have the highest priority for investment from the Health Service Provider's perspective. | | |
|----------------------------|---|--|--|
| System Manager | The term used for the Department of Health Chief Executive Officer to reflect his role as being responsible for the overall management of the WA health system (see section 19 <i>Health Services Act 2016</i>). | | |
| Useful life | The life span of medical and imaging equipment as per the Department of Health's useful life policy which is documented in the Department of Health's Financial Management Manual (Guide to Measurement of Assets and Depreciation). | | |
| WA health system | The WA health system is comprised of: (i) the Department; (ii) Health Service Providers (North Metropolitan Health Service, South Metropolitan Health Service, Child and Adolescent Health Service, WA Country Health Service, East Metropolitan Health Service, PathWest Laboratory Medicine WA, Quadriplegic Centre and Health Support Services); and (iii) contracted health entities, to the extent they provide health services to the State. | | |

8. Policy Contact

Enquiries relating to this Policy may be directed to:Title:Director, InfrastructureDirectorate:Major Health Projects and InfrastructureEmail:DOHInfrastructureMail@health.wa.gov.au

9. Document Control

| Version | Published date | Effective from | Review date | Amendment(s) |
|-----------|----------------|----------------|----------------|------------------------------|
| MP0110/19 | 24 June | 24 June | September | Original version |
| v.1.0 | 2019 | 2019 | 2020 | |
| MP0110/19 | 22 February | 22 February | February | Policy review undertaken and |
| v.2.0 | 2023 | 2023 | 2026 | major amendments below. |

• Updated information provided in the Policy Requirements and Compliance Monitoring sections.

• A definition for 'Assets', 'Refurbished medical equipment' and 'WA health system' has been included in the Definitions section.

• Removal of the Medical Equipment Management Reporting Template and inclusion of the MEMWG Terms of Reference in the Related Documents section.

10. Approval

| Approval by | Dr David Russell-Weisz, Director General, Department of Health |
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| Approval date | 31 May 2019 |

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