Department of Health

health

Medical equipment asset management framework

Parts A and B

State Government Victoria

Medical equipment asset management framework

Parts A and B

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Foreword

Victorian health services and the Department of Health share a strong interest in achieving quality and sustainable health outcomes through the most effective use and management of medical equipment.

Most Victorians only come face to face with medical equipment when they experience the healthcare system. It plays an integral role in health service delivery, and can range from simple items that largely go unnoticed by service recipients, to highly sophisticated and complex machines.

Medical equipment is increasingly important to health service provision and its significance is set to grow, driven by technological and clinical innovations and higher standards, alongside Victoria's need for sustainable service expansion. As an essential tool of trade of our health professionals, medical equipment must be professionally managed.

Each new generation of medical equipment can bring a rise in capability and performance. However, at times equipment improvements just keep pace with changes in health service delivery and may come at a greater overall cost, particularly as medical equipment is tending to be shorter lived.

These imperatives are at the genesis of the creation of this framework, which gives a consistent roadmap to assist each health service in their medical equipment asset management.

The framework articulates preferred practice and provides an opportunity to strengthen the response to medical equipment asset management challenges. The way the framework is taken up by health services will depend on the size and nature of the service, and on organisational asset management maturity and governance already in place. Applied as intended, the framework should aid in minimising risks and sustaining maximum service benefit, thereby achieving the best value for money from medical equipment.

This framework is the result of collaborative effort between health services, and the department and I would like to thank those who generously contributed their time and expertise to develop, test and refine it. The framework should be of particular interest to hospital and health service clinicians and management, who can use it to support their effective management of the medical equipment assets and services under their control.

I commend this *Medical equipment asset management framework* to you as a resource to assist with managing medical equipment. I look forward to its adoption as you plan, acquire, operate, maintain and dispose of medical equipment.

Lance Wallace
Acting Secretary

Contents

Summary

The management of physical assets can be a confronting business. Medical equipment, a specialised kind of asset, presents some unique challenges. Many items of medical equipment are technically complex, requiring specialist expertise to use, manage, assess and repair them. They tend to have shorter lives than more traditional assets such as buildings and infrastructure, and hence require more focused and frequent attention. In a typical health service, they represent a considerable investment and operating cost, with potentially severe consequences following inadequate performance or failure.

The *Medical equipment asset management framework* (MEAMF) recognises these characteristics and provides principles, practices and techniques designed to assist users and managers in managing medical equipment assets. It aims to ensure equipment meets clinical requirements, is effectively maintained, is replaced when and only when it needs to be, and that additional equipment is acquired when needed. All this has to be accomplished in a constrained environment for both capital and operating costs.

Part A of this document is an overview of MEAMF, which summarises the key features for management.

Part B is for users, practitioners and decision-makers, and has five sections that outline the framework. The first section emphasises the importance of accessible and reliable information about equipment, without which effective management is difficult. The remaining four sections of Part B track the stages of the asset lifecycle: plan, acquire, operate and dispose.

This framework relies upon the use of some standardised approaches, for example, common nomenclature and effective life baselines. Their use improves communication, reduces wasted time, and assists with prioritisation and budgeting. They do not replace the continuing need for long-term strategic thinking, and for the thoughtful assessment of the results of detailed analyses and procedures.

The five sections of the framework present recognised sound practices for each stage as they apply to medical equipment and are represented in the following graphic, which is used to aid navigation through the document. The contents of Part B are durable and not expected to change rapidly.

Part C (MEAMF tools) is a companion document available online that provides information and support for Part B. It contains information sheets, templates, checklists and packages to ensure a consistent approach throughout the Victorian Department of Health and health services. Provision is made for these documents to be updated or added to in the light of operating experience, technical advances or procedural changes.

Overview of the *Medical equipment asset management framework*

A

Introduction

Medical equipment is essential to the delivery of healthcare and represents a significant proportion of the total asset base of individual health services. The management of medical equipment is one of the main risk-critical issues to keep health services functioning because the unavailability of equipment or failure of equipment presents risks to patients, staff and service delivery. These risks need to be managed effectively and efficiently.

The primary goal of asset management is to enable an organisation to meet its service delivery objectives efficiently and effectively, and minimise the risk associated with asset failure.

Managing the risk includes sustaining existing equipment capacity and planning for timely replacement. The risk of equipment failure increases as medical equipment approaches the end of its effective life. Lack of reliable and timely information makes it difficult to properly forecast and plan equipment requirements to meet service needs and take account of financial requirements. The assets themselves are technically complex and short-lived, and present a significant management challenge.

Effective asset management also maximises the service potential of assets by increasing flexibility and using economies of scale for more cost-effective service delivery. These factors led to the development of this *Medical equipment asset management framework* (MEAMF), which comprises two parts:

- **Part A** (this part) is for managers and decision-makers. It provides an overview of the framework and the rationale for its development.
- **Part B** provides detailed information for users, practitioners and decision-makers who deliver the programs.

An additional companion document (Part C) is also provided to assist MEAMF implementation.

- **Part C** includes further resources such as information sheets, checklists and templates.

Asset lifecycle

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Medical equipment, like all other assets, passes through a lifecycle of: planning; acquisition; operation and maintenance; and disposal (Figure A.1). Asset management is a continuous process encompassing each of these stages.

Figure A.1: Asset management over the lifecycle of an asset

Source: Victorian Department of Treasury and Finance[1]

Best practice asset management principles and the asset lifecycle apply to the management of medical equipment assets. They provide the basis for the MEAMF as shown in Figure A.2. The MEAMF outlines how the whole-of-government approach relates to public health service medical equipment assets.

This approach to asset lifecycle planning is applied across all government departments and is based on preferred practice in government and industry. *Sustaining our assets*[2] presents key asset management principles and expectations for managing assets at each of the lifecycle stages, which have been government policy since 1993.

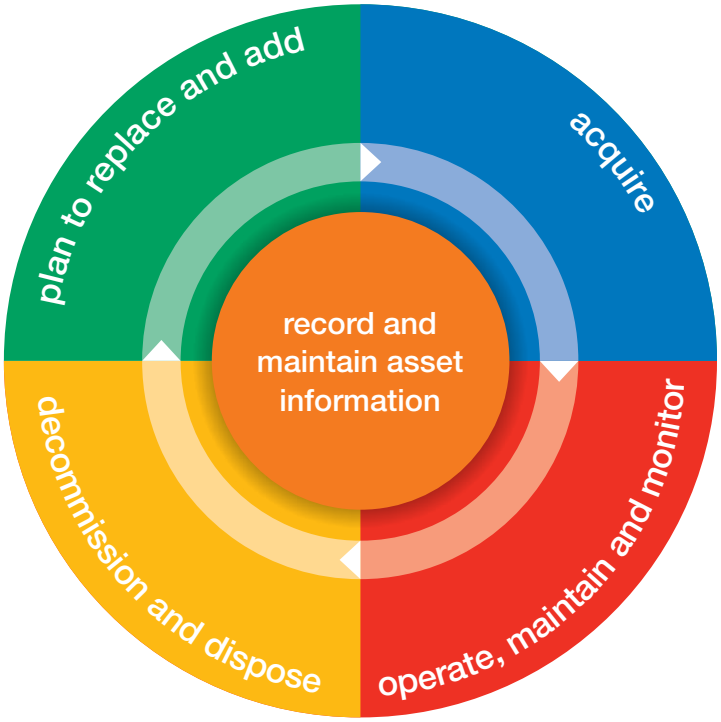
1 www.dtf.vic.gov.au/CA25713E0002EF43/pages/asset-management-in-the-victorian-public-sector-asset-management-framework (Quicklinks>Asset management policy>Asset management framework)

2 Department of Treasury and Finance 2000, *Sustaining our assets*, Government Asset Management Policy Statement, State Government of Victoria, Melbourne. www.dtf.vic.gov.au/CA25713E0002EF43/WebObj/SustainingOurAssets/$File/Sustaining%20Our%20Assets.pdf.

Accordingly, asset management should:

- clearly assign ownership and control of assets
- optimise the service potential of assets to ensure they are appropriately used and maintained
- reduce or delay the need for assets
- deliver greater value for money through evaluating service delivery options that take into account the full lifecycle costs of assets
- focus on asset performance and assign responsibility, accountability and reporting requirements
- integrate planning, budgeting and reporting on assets with broader planning processes
- consider non-asset and asset-based options, and both qualitative and quantitative measures when deciding on possible investment.

Figure A.2: The five stages in the lifecycle of medical equipment assets



Responsibilities for medical equipment asset management

A

The Victorian Department of Health and health services

The department and individual health services have complementary roles to play in asset management to ensure delivery of quality services.

The department sets out the policies for delivering health services in Victoria, determines standards, and allocates resources within frameworks and designated budgets.

Individual health services develop programs and service delivery strategies to incorporate policy and to meet the needs of the community they serve. Asset management is an essential part of these programs and strategies, with each individual health service responsible for managing its own assets and allocating responsibilities for each stage of the asset lifecycle.

The sharing of reliable and timely information and the formulation of asset management plans by each health service are essential to effective collaboration between health services and the department.

Governance of health services

Health services operate within a governance framework that defines the roles and responsibilities of the board, the chairperson and the chief executive officer (CEO). In essence, the board sets strategic directions in accordance with government policies, and delegates responsibility to the CEO for day-to-day management.

The CEO holds the day-to-day responsibility for the management of medical equipment. This requires strategic planning, establishment and maintenance of effective systems. Ongoing review and redesign is also needed to provide high-quality, effective and essential healthcare services that are governed and managed effectively, efficiently and economically, and that are accountable to the public.

Asset management within health services

The management of medical equipment assets is a complex multidisciplinary activity that extends over the entire lifecycle of the asset. Different assets require some differences in management, and responsibilities may shift as the asset moves through the stages of its lifecycle.

Therefore, the clear assignment of responsibility for asset performance is of critical importance. Health service management may need to pay particular attention to:

- operating comprehensive, integrated systems for asset management information
- identifying team leaders when multidisciplinary teams are involved
- encouraging a ‘lifecycle’ approach to asset decision making, even when the immediate responsibility of the manager is for one stage of the cycle.

Guidance on the effective allocation of responsibilities is provided in each section of the MEAMF in Part B.

Medical equipment asset management framework

The MEAMF has been developed to improve medical equipment asset management in Victoria and, in particular, to help individual health services meet their risk responsibilities. The MEAMF involves a broad range of stakeholders across health services and industry groups including the metropolitan and regional CEO groups, the Industry Finance Committee and the Biomedical Engineers Focus Group.

The MEAMF provides guidance and information to help Victorian public health services to manage their medical equipment assets using a consistent approach, and to meet the Victorian Government requirements for asset management.

Key features of the MEAMF are:

- the importance of comprehensive asset information, with swift access to reliable asset data
- standardised guidelines for classifying and defining medical equipment assets, including standard nomenclature
- critical risk prioritisation
- realistic estimates of 'effective lives' for medical equipment, with regular review
- systematic monitoring of 'fitness for purpose', with immediate feedback to the asset planning and procurement functions
- comprehensive forward planning and budgeting for replacement equipment.

Available online, the MEAMF tools are provided in a companion document in Part C.

These standardised tools, guidelines and templates help health services to develop, implement and maintain their individual asset management plans.

A

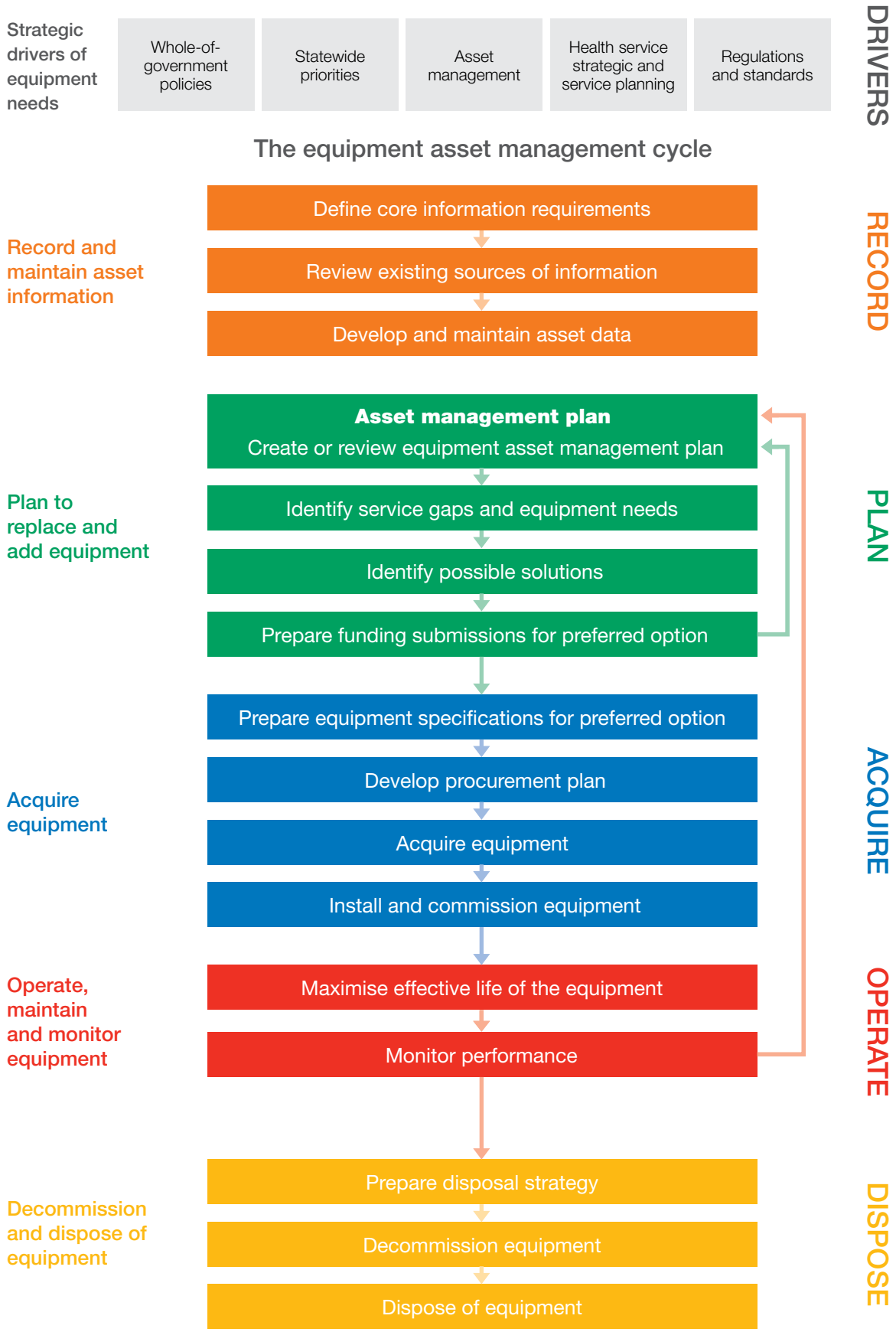
Benefits of the framework

Adopting a standardised and consistent risk-based approach to managing medical equipment will enable:

- more effective longer term forward planning
- health services to
  - more robustly plan equipment requirements
  - develop systems to plan and acquire medical equipment assets according to business principles
  - optimise decision making on investments in medical equipment
  - use methods to monitor, record, evaluate and report on medical equipment asset management actions
  - improve the quality and safety of healthcare for Victorians in public health services
  - recognise whole-of-lifecycle costs and operating costs associated with investments
  - develop asset management plans
- enhanced targeting of resources to highest risk equipment
- greater transparency in the allocation and prioritisation of medical equipment
- more timely allocation of funds to health services.

The key activities and decision points in the MEAMF are shown in Figure A.3.

Figure A.3: Key decision points for medical equipment asset management



Note: Key decisions are shown as linear to clearly identify the components in a logical flow. It is acknowledged that many processes involved may be occurring concurrently and will be feeding back into differing components.

Sources: Victorian Healthcare Association 2005, *Health service capital expenditure review*; Auditor-General Victoria 2001, *Review of capital equipment funding strategy for Victorian public hospitals*; Monash University Centre for Biomedical Engineering 1995, *Capital investment in Victorian public hospitals*; and literature reviews.

A

Scope of the framework

What is medical equipment?

Under the Australian Standard AS 3551:2004 — *Technical management programs for medical devices*,[3] the definition of a 'medical device' is:

> Any instrument, apparatus, or appliance, including software, whether used alone or in combination, together with any accessories necessary for correct operation, which 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.

For the purposes of this framework, the term 'medical equipment' does not include:

- prostheses, implanted or externally worn items
- buildings
- infrastructure maintenance or works
- motor vehicles
- plant, furniture and fittings
- information technology equipment.

Which areas of healthcare are included?

The MEAMF applies to medical equipment assets located within the following areas of healthcare:

- acute
- subacute
- aged care
- mental health
- public health
- dental health services
- primary health.

3 AS/NZS 3551:2004 — *Technical management programs for medical devices*, Standards Australia/ Standards New Zealand (https://infostore.saiglobal.com/store/Details.aspx?ProductID=373238).

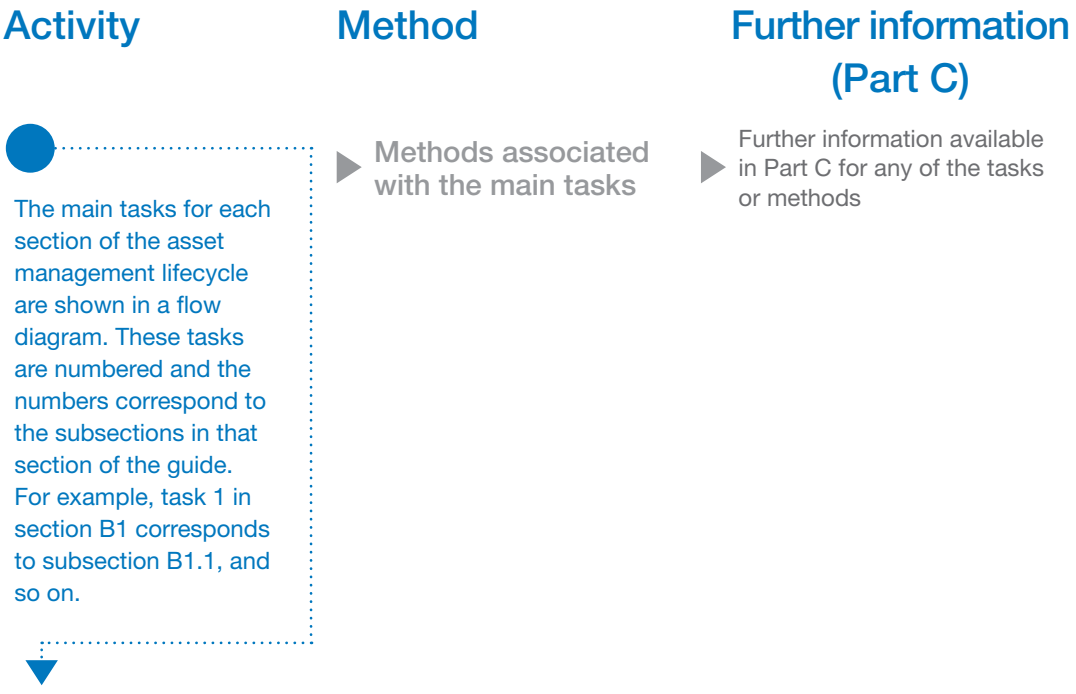
How to use Part B of the framework

Part B is the framework and has five sections, which are based on the five stages of medical equipment asset management shown in Figure A.2. Each section consists of a series of clearly defined steps or actions that are required to complete that stage of the process:

- section B1: Record and maintain asset information
- section B2: Plan to replace and add equipment
- section B3: Acquire equipment
- section B4: Operate, maintain and monitor equipment
- section B5: Decommission and dispose of equipment.

To help readers find the information they need, each section in Part B has an activity diagram, which has the following components:

Activity diagram — components



How to use Part C – MEAMF tools

A

Available online, **Part C** is a companion document that has a series of individual resources ('tools'), each with its own cover page and cross-referenced to the sections and subsections of Part B. There is a contents page to direct readers to the tool that may be required.

Part C includes components that are subject to more frequent updates. These will be added as they are developed (in accordance with operating experience, technical advances or procedural changes) or removed when no longer relevant or required. Updates will be added to the online version of this document at: www.health.vic.gov.au/med-equip

Medical equipment asset management framework

B

Record and maintain asset information

B 1

Overview

Good asset management relies on appropriate and up-to-date asset data with well-defined inclusions and exclusions.

Managers and decision-makers need access to information that includes operating performance, risk-level profile, estimated life, maintenance programs, values and costs, and many other parameters. This information may be incomplete, inaccurate, held in a number of unlinked databases or not captured at all. The consequences include time-consuming and expensive searches to create or recover vital core management information when it is needed, or acceptance of the risks associated with decisions made with inadequate data.

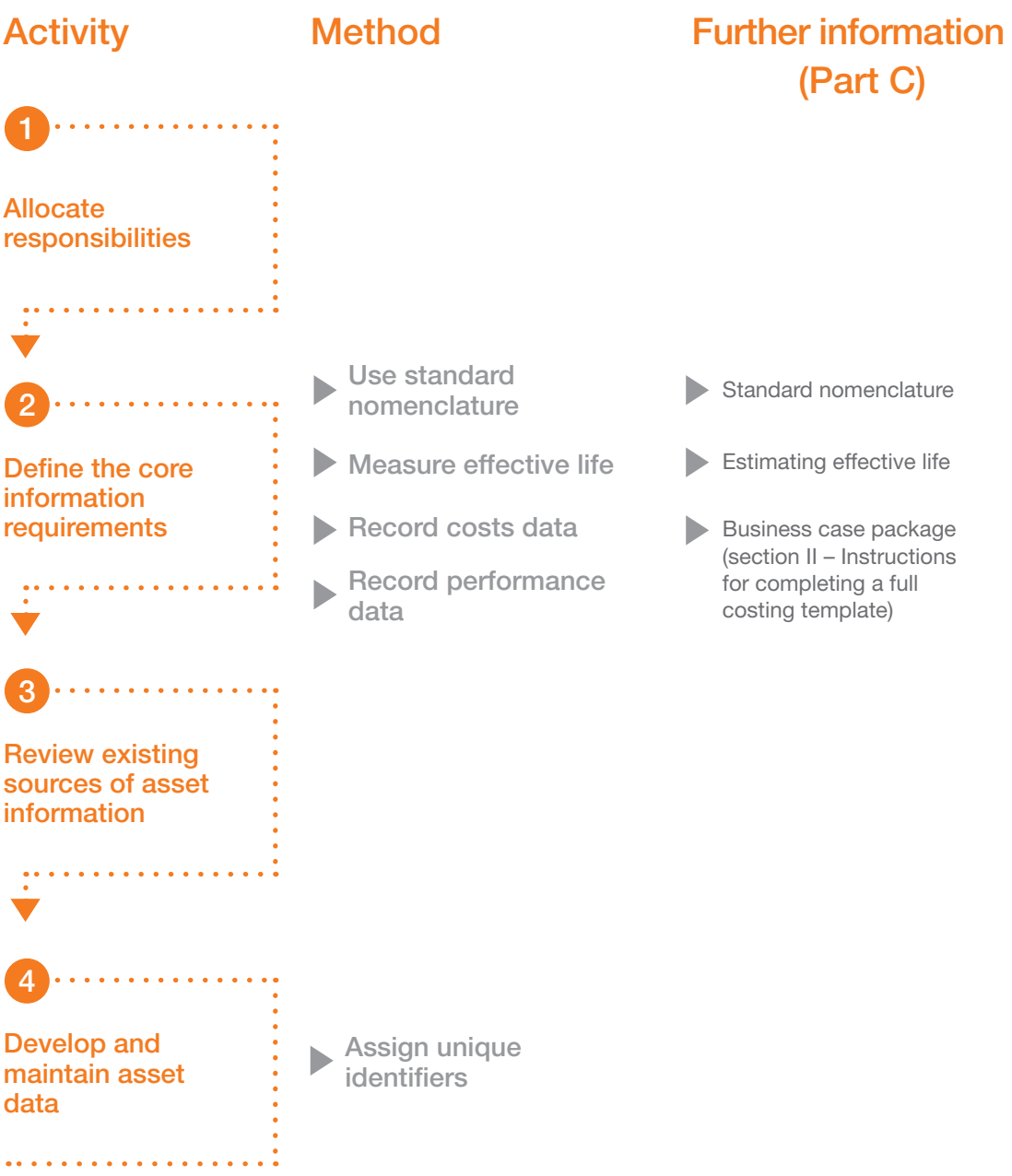
As many medical equipment assets are short-lived, regular validation and reconciliation of asset data are required to ensure all additions and archived records of former assets are clearly identified. Where information about an asset is recorded in multiple databases, reliable procedures are required to ensure data is maintained consistently and accurately.

In order to set up and maintain timely and accurate information on assets, health services need to:

- allocate responsibilities to record and maintain asset information
- define the core information requirements
- review existing sources of information
- develop and maintain asset data.

Activity diagram 1 shows the activities involved in achieving these aims and the methods to be followed, and refers to the supporting information and tools available.

Activity diagram 1 — Record and maintain asset information



1

1.1 Allocate responsibilities

▶ **See also sections 1.3 and 1.4** below for further information about sources of asset information and developing and maintaining asset information

The responsibility to establish and maintain adequate information on medical equipment assets usually lies with the area of the health service that uses those assets.

Where sources of asset information are dispersed and fragmented, for example into a financial asset register and a maintenance management system, health service management will need to allocate single-point responsibility for the integration of asset data, regardless of source.

2

1.2 Define the core information requirements

Good asset management relies on well-maintained, authoritative and readily accessible asset data that contain complete and up-to-date information on the acquisition, operation, maintenance and disposal of assets.

For asset information to fully support strategic planning and management, it should:

- include all equipment assets under the control of the health service
- support the structured classification system for equipment
- use a unique identifier for each asset that is maintained across all data systems and throughout the lifecycle
- have procedures, controls and audit trails to maintain the integrity of the information
- identify the individual or business unit accountable for the equipment and its location
- record the financial information needed for management and statutory reporting
- track the asset through its lifecycle from purchase to disposal
- be readily accessible to individuals who are accountable for the control and management of a nominated equipment item or systems, preferably on a ‘real-time’ basis.

1.2.1 Use standard nomenclature

Standard nomenclature must be used for medical equipment assets. Using standard nomenclature to classify a product or group of similar products enables health services and the department to share information more effectively. This information sharing has a number of benefits including:

- improved compliance with regulatory requirements and conformity assessments for product registration with organisations such as the Therapeutic Goods Administration
- consistent incident reporting and device recall notification
- increased clarity in procurement (equipment specifications)
- better inventory management (consumables)
- improved asset management, reporting and replacement planning
- improved device lifecycle tracking (maintenance history).

✱ Refer to Part C
– 'Standard nomenclature'

The use of standard nomenclature is also particularly important when asset data are held on more than one database.

1.2.2 Measure effective life

The estimation and monitoring of effective life is a critical item of data for medical equipment. 'Effective life' is the period over which an item of medical equipment can provide the required function or service for a health system. It is developed using manufacturer's data, service histories, and the expertise of senior technical and clinical staff.

✱ Refer to Part C
– 'Estimating effective life'

The accounting standards depreciation schedule does not always reflect an individual asset's effective life. In some cases, an asset may still have remaining effective life when it is fully depreciated. Reviews both in Australia and overseas[1] have found that significant proportions of medical equipment assets are retained in use beyond the period for which they have been fully written down for financial purposes.

▶ **See also section B2.3.3** for further information about estimating effective life

Because of the importance of effective life data, an effective life tool has been provided, which brings a consistent approach to the development of estimates. Effective life estimates and re-estimates should be recorded using this tool.

1 Victorian Health Care Association Ltd 2005, *Health service capital expenditure and management review*; Audit Scotland 2001, *Equipped to care: managing medical equipment in the NHS in Scotland*; Audit Scotland 2004, *Better equipped to care? Follow-up report on managing equipment*.

1.2.3 Record costs data

Asset information systems should record cost data for individual items of equipment.

Lifecycle costing is a core technique for evaluating service delivery options that require the use of medical equipment assets. This approach determines the sum of all the costs associated with an asset or part thereof, including acquisition, installation, operation, maintenance, refurbishment and disposal, and is a key part of the asset planning process. The cost information that needs to be held as asset data includes initial acquisition costs, as well as operating and maintenance costs.

✱ Refer to Part C
– 'Business case package (section C2)'

Acquisition costs to be recorded include:

- initial acquisition costs (such as delivery charges, capital works and installation)
- integration and interface costs (connections to other equipment and systems)
- staff training and education (both for new and experienced users).

The acquisition date should be recorded.

Operating and maintenance costs to be recorded include:

- scheduled upgrades or refurbishments
- maintenance costs
- repair costs
- spare parts and accessories
- supplies and consumables
- waste disposal
- utilities (such as energy)
- insurance
- licences
- staff training and education (new and experienced users)
- accreditation and certification training
- depreciation
- end-of-life disposal costs.

▶ See also section B2.5 for further information about preparing a business case

1.2.4 Record performance data

Examples of performance data include:

- measures of the operational performance and benefits of the equipment in relation to its service delivery objectives (both quantitative and qualitative)
- measures of how intensively the equipment is used
- reliability (incident reports, performance failure)
- maintenance episodes
- operating costs (consumables, repairs and maintenance expenditure)
- expected effective life.

Where possible, these measures should be benchmarked (within or across health services) or evaluated against best practice data to see how the equipment is being managed.

3

1.3 Review existing sources of asset information

In an ideal situation, a single-asset database would contain all of the information identified above. In many cases, as no single-asset information system is able to meet the needs of all the different groups in a health service, assets are typically managed using different software packages in different departments areas within the service. This may result in the information concerning a particular asset being fragmented along functional divisions (financial, clinical service delivery, maintenance).
In many cases, the primary source of financial information is usually the financial asset register, which may be part of a comprehensive financial management information system. Maintenance and spare parts data may be held in a separate maintenance management system operated by the relevant department or organisation responsible for managing equipment service.

▶ See section 1.4 below for further information on developing and maintaining asset information

Ideally, the different asset information systems would be linked so that the discrete information relevant to one health service department could be shared by all the parties interested in a particular asset. In practice, asset systems are often not linked and do not update each other automatically. A review undertaken in Victoria in 2007 found that almost all (metropolitan, regional and rural) health services operated more than one asset database.[2] In most cases, these consisted of the financial asset register and a separate biomedical or engineering database. Ways in which these data can be combined or synchronised with the operational data should be assessed.

The review of systems in use should focus on:

- the extent to which the systems collectively accommodate the functional requirements outlined above (in particular, the ability to use standard nomenclature)
- the level of data integrity and security provided in proprietary databases and spreadsheets
- the ability to synchronise the systems (either by periodic updating or in real time)
- the need for a consistently applied unique identifier for all items.

4

1.4 Develop and maintain asset data

Initial data capture and validation can be a major one-off task, depending on the opportunities for the electronic transfer of data from existing systems. Given the amount and range of data needed, and the likelihood that some of it has not yet been recorded, some manual data capture and entry may be necessary.

2 Department of Human Services 2007, *MEAMF nomenclature impact and asset registers — project findings report*, State Government of Victoria, Melbourne.

When an asset is acquired, it must be allocated a unique identifier that will be used for the life of the asset in each different asset information system in the health service. When the asset is retired and is disposed of, the unique identifier is also retired and archived. The replacement asset must not carry the same identifier as the asset it replaces. In cases where an asset has had previous identifiers, it is essential that the connection and mapping of these are evident in the asset data.

All additions to the asset base and transfers to archives should be recorded in every relevant information system. In the absence of linked information systems, health services need to design and implement manual systems to ensure all relevant information is collated and assembled for each asset.

Asset information should be reliable, accessible and complete, and ideally be available as a single asset data source. The following issues may apply:

- The financial asset register needs to be kept in a form that maintains the integrity of the data for the financial statements. Some financial registers do not have the ability to accommodate the additional performance and engineering information needed (or the standard nomenclature).
- Biomedical, engineering and imaging databases need to be able to disaggregate assets (as identified in the financial asset register) into components and subcomponents, and to record spare parts and maintenance data.

There is often overlap between biomedical and engineering databases, and these databases should be linked or combined if possible (and incorporate standard nomenclature).

As a minimum step, and if the continuing operation of a separate financial asset register and the biomedical or engineering registers is expected, action should be taken to align all asset systems with the standard nomenclature, and to devise regular updating routines and protocols to ensure consistency and ready access to full information.

Further reading

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Plan to replace and add equipment

B 2

Overview

Asset planning is the most critical stage of the equipment asset management lifecycle. It determines whether and when existing equipment is replaced or additional equipment purchased, and ensures that equipment assets closely match service delivery requirements. Planning for medical equipment requirements is a comprehensive multidisciplinary activity that takes into account a range of factors including the:

- equipment lifecycle and asset management principles[1]
- needs of patients and staff delivering patient care
- policy and legislative environment
- health service's corporate management and planning requirements
- technical adequacy and clinical effectiveness
- external or market factors, such as environmental issues
- competing demands of stakeholders and other funding priorities
- advantages available by using new technologies
- expectation of improved service delivery and cost-effectiveness.

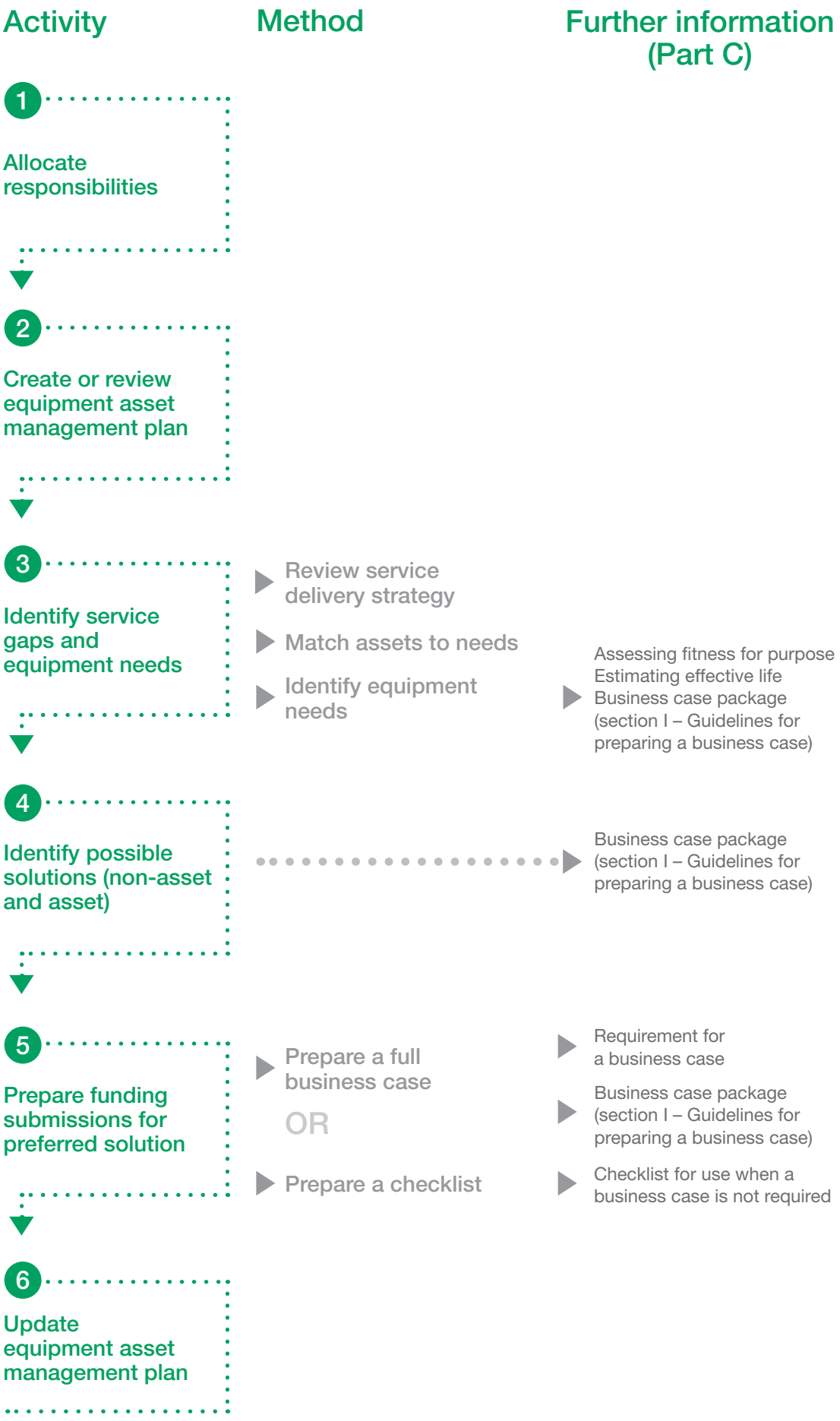
The activities involved in asset planning include to:

- allocate responsibilities for planning
- create or review and update the equipment asset management plan
- identify service gaps and equipment needs
- identify possible solutions (non-asset and asset)
- prepare funding submissions (internal and external) for the preferred solution.

Activity diagram 2 outlines these activities and identifies the supporting information and tools available in Part C.

1 Department of Treasury and Finance 1994, *Asset Management Series: Principles, policies and practices*, State Government of Victoria, Melbourne. www.dtf.vic.gov.au/CA25713E0002EF43/WebObj/AssetManagementSeriesPart1/$File/AssetManagementSeriesPart1.pdf

Activity diagram 2 — Plan for replacement and additional equipment



1

2.1 Allocate responsibilities

Planning to add or replace equipment is the responsibility of the health service that owns or has contracted the use of the equipment.

Planning is a multidisciplinary activity and typically involves the range of skills needed to cover both operational aspects (such as service delivery requirements, biomedical engineering) and commercial considerations (procurement, funding, budgeting). These skills may reside in different parts of the organisation.

Health service management will need to ensure the necessary skills are available and that responsibility is allocated to a team leader to produce an integrated planning result.

2

2.2 Create or review equipment asset management plan

2.2.1 The medical equipment asset management plan

Medical equipment planning must be undertaken and managed within a framework driven by service delivery needs and strategies that align with statewide strategic and service plans. Assets are to be monitored and evaluated using a continuous improvement approach throughout their lives, with asset management policies and practices aligned with the MEAMF.

Medical equipment asset management plans are required to cover a five to 10-year planning period and be reviewed and updated on a rolling basis every two years. The following applies to creating an asset management plan and to reviewing an existing asset management plan.

2.2.2 Objective

The objective of the medical equipment asset management plan is to establish and maintain a management program to promote safe, effective and efficient use of medical equipment to support patient care and minimise risk through responsive and efficient planning, acquisition, use, and disposal of medical equipment assets.

2.2.3 Principles

Medical equipment asset management plans should:

- be within a strategic asset management framework
- be consistent with corporate and business planning and budgetary reporting processes
- integrate with other key management strategies that guide asset management practices and decisions
- adopt a lifecycle approach to consider the effects of decisions made throughout the lifecycle.

2.2.4 Governance of medical equipment asset management plans

The health service medical equipment asset management plan should be accountable, transparent and lead to quality reporting.[2]

The health service board should be regularly informed about the status of medical equipment: asset performance, risk posed, planned investment, management and disposal.

2.2.5 Content of medical equipment asset management plans

The development of asset management plans for medical equipment will be progressive, iterative and will need to be consistent with the scale of the service and operation and complexity of medical equipment. A number of iterations are likely to achieve a comprehensive asset management plan.

A comprehensive asset management plan for medical equipment for large and complex service and medical equipment inventory should have the following components.

Acquisition plan

This plan — for all projected replacement and additional equipment — defines equipment to be acquired in the planning period, and establishes the sources and cost of funding for acquisitions. The full cost of acquiring, operating and maintaining the equipment needs to be taken into account in the planning processes, along with the related risks and benefits.

2 Victorian Government Department of Treasury and Finance 2000, *Sustaining our assets*, Government Asset Management Policy Statement, Victorian Government, Melbourne.

For example, maintenance plans and contracts need to be considered at the time of acquisition to optimise whole-of-lifecycle costs and contract pricing.

The acquisition plan should consider:

- the existing stock of medical equipment, its fitness for purpose, and estimated effective life
- the clinical services that the equipment supports, including expected changes in the demand or nature of those services
- contingency plans for high-risk mission-critical items of equipment
- opportunities for 'non-asset' solutions such as redesigning or outsourcing the service, or securing access to the asset without ownership
- the full lifecycle cost of proposed acquisitions.

Operations plan

This plan covers all equipment and defines the use of existing assets. It should include responsibility for the equipment, security, accountability and arrangements for monitoring performance. Management processes should be established and maintained efficiently and effectively. The physical, operational, functional and financial performance of equipment, training and operating costs should be routinely monitored, with processes set in place to address performance deficiencies and increase performance.

The operations plan should include:

- a clear definition of responsibilities and accountability for operational management, cost control and reporting
- workforce skill requirements and training arrangements
- compliance standards, regulations and licensing
- planned approaches to optimise the service potential of the equipment
- identification of any limitations or special applications of the equipment
- regular monitoring of performance, fitness for purpose and effective life.

Maintenance plan

This plan covers all equipment and defines which assets are to be maintained, and the level and timing of maintenance to be undertaken, to keep them fit for purpose and achieve the required performance standards

with the most cost-effective use of maintenance resources. Effective asset maintenance should optimise service and equipment life, reduce long-term lifecycle costs and deliver on an asset's service and safety standards.

The maintenance plan should consider:

- the services and warranties available from the supplier
- the necessary standard of maintenance required to ensure the equipment is available when required to perform its function
- any requirements to hold spare parts or consumables
- whether in-house or contract resources are appropriate
- the recording of performance data and maintenance history
- the possible use of performance-based contracts.

Opportunities for 'cascading down' equipment to a less critical application should be considered prior to disposal.

Disposal plan

This plan covers all equipment expected to be replaced or reach the end of its effective life during the planning period. Consideration should include expected proceeds on disposal and use of the proceeds.

The disposal plan should consider:

- requirements for decontamination prior to disposal
- environmental management
- allocation of responsibilities for removal and remediation of the site as necessary
- optimising the proceeds and nominating their proposed use.

Risk management plan

This plan is for all equipment and describes the risk management strategies and actions to be implemented to control the risks associated with the equipment. Risk management strategies must be invoked as equipment items experience deterioration in performance or approach the end of their effective life.

2.2.6 Evaluation of asset management plans

Medical equipment plans should demonstrate that service delivery is being met efficiently and effectively by:

- maximising service potential of existing assets by ensuring appropriate usage and maintenance
- considering demand management techniques and alternative service delivery options
- achieving value for money throughout the acquisition and ongoing management of the equipment.

Structured reviews and updating of asset management plans should be undertaken regularly and at least every two years.

✱ Refer to Part C – 'Equipment asset management planning'

▶ See section 2.6 below for further information on updating the asset management plan

3

2.3 Identify service gaps and equipment needs

2.3.1 Review service delivery strategy

Government strategic and health service plans, and service delivery strategies specific to each health service, provide the basis for asset planning and identification of equipment needs. Matching the medical equipment requirements of the health services to their medium-term service delivery strategies should ensure that medical equipment is consistent with the scope, capacity and performance of the service required.

The service delivery strategy includes information on:

- the types of services or procedures provided
- the number of services or procedures provided
- service capacity
- patient waiting times for procedures involving the proposed equipment
- patient profile and mix (public, private)
- service demand, level of use, burden of disease
- fitness for purpose, use and effectiveness of equipment (its capacity to sustain service delivery)

- relationships with other service providers and models of care
- the workforce.

The service delivery strategy can change over time as circumstances change and operating experience is gained. External influences that may prompt change include:

- changes in the profile of the number, type and mix of patients
- impacts of Australian Government, and state and local government policies and strategies
- changes in legislation, regulations, standards and accreditation requirements
- strategic and service plans of other health service providers
- changes in medical technology and practice.

The asset planning process begins with a description of the existing needs and demands for services, and the projected future levels of service provision, based on the planning horizon.

2.3.2 Match assets to needs

Matching assets to needs involves a thorough examination of why a particular item of equipment is needed and consideration of the full range of options for responding to the need. These options may include both non-asset-based and asset-based solutions, as well as demand management strategies. For example, a particular health service may have multiple ultrasound units in the health service, hospital or department/area, and the needs analysis should clearly identify why a replacement or additional ultrasound may be required (in relation to the specific service involved).

Asset planning and identification of equipment needs allows priorities to be determined and justified. These priorities should be regularly reviewed and may need to be updated to reflect, for example, impacts from changes in technology, service delivery methods or the cost of equipment.

Horizon scanning

As new medical technologies or improvements in existing technology develop, equipment becomes available that could signal important changes in, or impact significantly on, patient care, health outcomes or the healthcare system.

'Horizon scanning'[3] may identify, track or monitor new and emerging technologies. It should be undertaken before major acquisitions are considered. Horizon scanning is a specialised activity that provides short, rapidly completed, 'state-of-play' documents containing current information.

Horizon scanning provides information on new and emerging technologies, which is often limited, to alert planners, policy-makers and funders of the potential impact of new technologies, in terms of safety and cost, before they are introduced into the health system.

The purposes of horizon scanning is to assist planners and policy-makers to:

- identify new technologies that have potential major implications for the health system
- assist in the control of technologies in the health system
- rationalise adoption and use of new technologies
- assess areas of technological change
- identify under-used technologies
- anticipate future long-term needs
- prioritise and allocate resources.

Horizon scanning can also provide timely information about changes in the delivery and use of existing technologies.

Disinvestment

Disinvestment of an item of medical equipment — that is, its partial or complete and permanent withdrawal from active service — should be considered at key decision points during the life of the equipment.

When improved procedures are introduced into clinical practice, the superseded procedures may have associated medical equipment that then becomes redundant or inappropriate. Disinvestment to withdraw medical equipment in such instances should be a key planning and management consideration when alternative processes or technologies are being considered.

3 www.horizonscanning.gov.au

2.3.3 Identify equipment needs

▶ See also section B4.3 for further information on monitoring performance

Equipment in need of replacement during the planning period can be identified through maintenance regimes that include periodically assessing fitness for purpose and effective life, followed by risk assessments as appropriate.

These assessments should be included as part of the maintenance and performance-monitoring tasks that are routinely undertaken during the operational stage.

Assessment of fitness for purpose

✱ Refer to Part C – 'Assessing fitness for purpose'

A thorough assessment of fitness for purpose includes evaluating a range of factors in three categories: equipment performance, condition and functionality.

Estimation of effective life

✱ Refer to Part C – 'Estimating effective life'

The estimation and monitoring of effective life is a critical item of data for medical equipment. The initial estimates of effective life may have to be reduced (if, for example, spare parts are no longer available) or extended if the equipment continues to operate effectively and is adequately supported.

✱ Refer to Part C – 'Business case package' (section I: 'Guidelines for preparing a business case')

When equipment items are approaching the end of their effective life, or if the estimated life is modified after reassessment, a risk analysis is required to inform the appropriate action to be taken.

Additional equipment

The acquisition of additional medical equipment, either to increase the numbers of items of existing equipment or to acquire equipment with new functions or technology, may be considered when there are changes in the services delivered by the health service including:

- increased demand due to population growth
- demographic shifts in location or age structure
- a decision to increase standards of service, such as to reduce waiting times
- new or improved treatments for patient care
- measures required to deal with unexpected events, such as a pandemic.

▶ See also sections B1.2.2 and B4.3.3 for further information on effective life measurement

The reasons for the requests for additional or improved capacity should be documented (with reference to the appropriate government decision if a new or improved service is planned).

2.4 Identify possible solutions (non-asset and asset)

When deciding on the most appropriate option for dealing with an item of equipment that is approaching the end of its effective life, it is important to first establish:

- whether the service that the asset supports is expected to continue at the same or a similar level
- that the life of the existing asset can no longer be economically extended; that is, the asset needs to be replaced.

All available feasible options must be identified and evaluated, such as:

- not replacing the equipment but instead maintaining the existing item
- consolidating or reconfiguring existing equipment to improve the use of similar equipment
- alternative service delivery; that is, investigating how the service could be delivered without item replacement, such as providing the service at another site or using an external service provider
- refurbishing or upgrading the existing equipment
- replacing the existing equipment ('like with like'), noting that technological advances may result in the new equipment being significantly different to the item being replaced.

Possible funding options need to be included when evaluating solutions. These include outright capital purchase, operating leases and outsourcing.

A range of options should be considered for filling the need for additional equipment in a similar way to that for replacement equipment.

The benefits and costs (both qualitative and financial) of each of the realistic options must be analysed to identify the preferred option to meet the service need.

2.4.1 Qualitative analysis

Qualitative analysis involves evaluating the non-financial criteria of each short-listed option, which may include (but are not limited to):

- quality of healthcare (shorter hospital stays, faster recoveries, less invasive procedures)
- safety (for staff and patients)
- level of use (access to equipment, waiting times, throughput)
- fitness for purpose (alignment to the service-delivery strategy)
- integration and interface with other equipment (how well the chosen option can be integrated with other systems and equipment, such as the information systems and infrastructure already installed in the health service)
- workforce availability
- management issues (training, industrial relations)
- readiness to implement (potential difficulties with reliability, installation issues, staff training and so on)
- interdependencies and links to other projects.

Additional criteria for the evaluation can be developed by consulting key stakeholders.

2.4.2 Financial analysis

✱ Refer to Part C
– 'Business case package' (section II: 'Instructions for completing a full lifecycle costing template')

The aim of the financial analysis is to identify the total lifecycle cost of each short-listed option to enable comparison and selection of the best 'value-for-money' option.

The preferred option is determined by comparing the benefits and lifecycle costs of each option. The rationale for the chosen option should be clearly stated and supported by the outcomes of the comparative analysis. For example, reasons for selecting the chosen option could be that it:

▶ See also section B1.2.3 for further information on recording costs data

- improves treatment outcomes
- meets current demand, as well as known and future emerging growth
- increases efficiency and throughput
- reduces patient waiting times and costs resulting from downtime and maintenance of faulty or less-than-efficient equipment.

The preferred option should also align with the service objectives of the health service, the department, and whole-of-government strategic directions where appropriate. Stakeholder support for the preferred option should be stated.

Any special implementation issues must be considered and described as part of the business case.

Aspects that must be considered for acquisitions include:

- project management and governance
- composition of the project team
- stakeholder involvement
- the cost and operational impact of consequential building works and services
- transition arrangements
- opportunities for disposing of the equipment to be replaced.

5

2.5

Prepare funding submission for preferred solution

If the preferred solution is to acquire and there is funding available, the final tasks in the asset-planning stage are to develop a business case or checklist for each proposed acquisition, and to consolidate the planned acquisitions to generate a funding forecast for the planning period.

2.5.1 Prepare a full business case

A business case is required for the following acquisitions:

✱ Refer to Part C
– 'Requirement for a business case'

- when requesting capital funding for replacement equipment above the current threshold
- when requesting capital funding for additional equipment above the current threshold
- when seeking permission for leasing medical equipment
- as requested by the department.

✱ Refer to Part C

– 'Business case package' (section III: 'Instructions for completing a business case template')

A business case should include:

- identification of strategic drivers
- development of options and lifecycle costing
- an options assessment (qualitative and quantitative)
- justification of the preferred option.

✱ Refer to Part C

– 'Checklist for use when a full business case is not required'

2.5.2 Prepare a checklist

A formal business case is not mandatory when purchasing assets costing less than the current threshold.

The information required to assist health services to evaluate proposed acquisitions when a business case is not required is provided in Part C.

6

2.6 Update equipment asset management plan

The updating of the asset management plan requires, at a minimum, updating of the acquisition plan to present the most consolidated list of planned acquisition.

The consolidated list of planned acquisitions for the planning period forms the basis of the updated asset management plan. The remaining components of the plan that should be completed are:

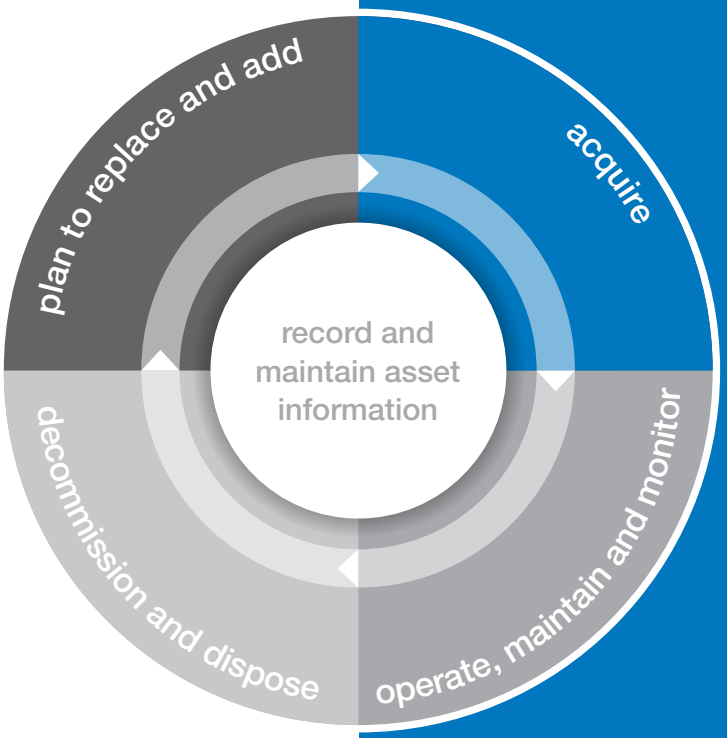
- the disposal plan, identifying all equipment assets that will reach the end of their effective life, or that are planned to be replaced, during the planning period
- the operations and maintenance plan, covering all equipment assets that are planned to remain in service.

▶ See also section B1.4 for further information on maintaining asset data

All asset data should be updated appropriately.

Acquire equipment

B 3



Overview

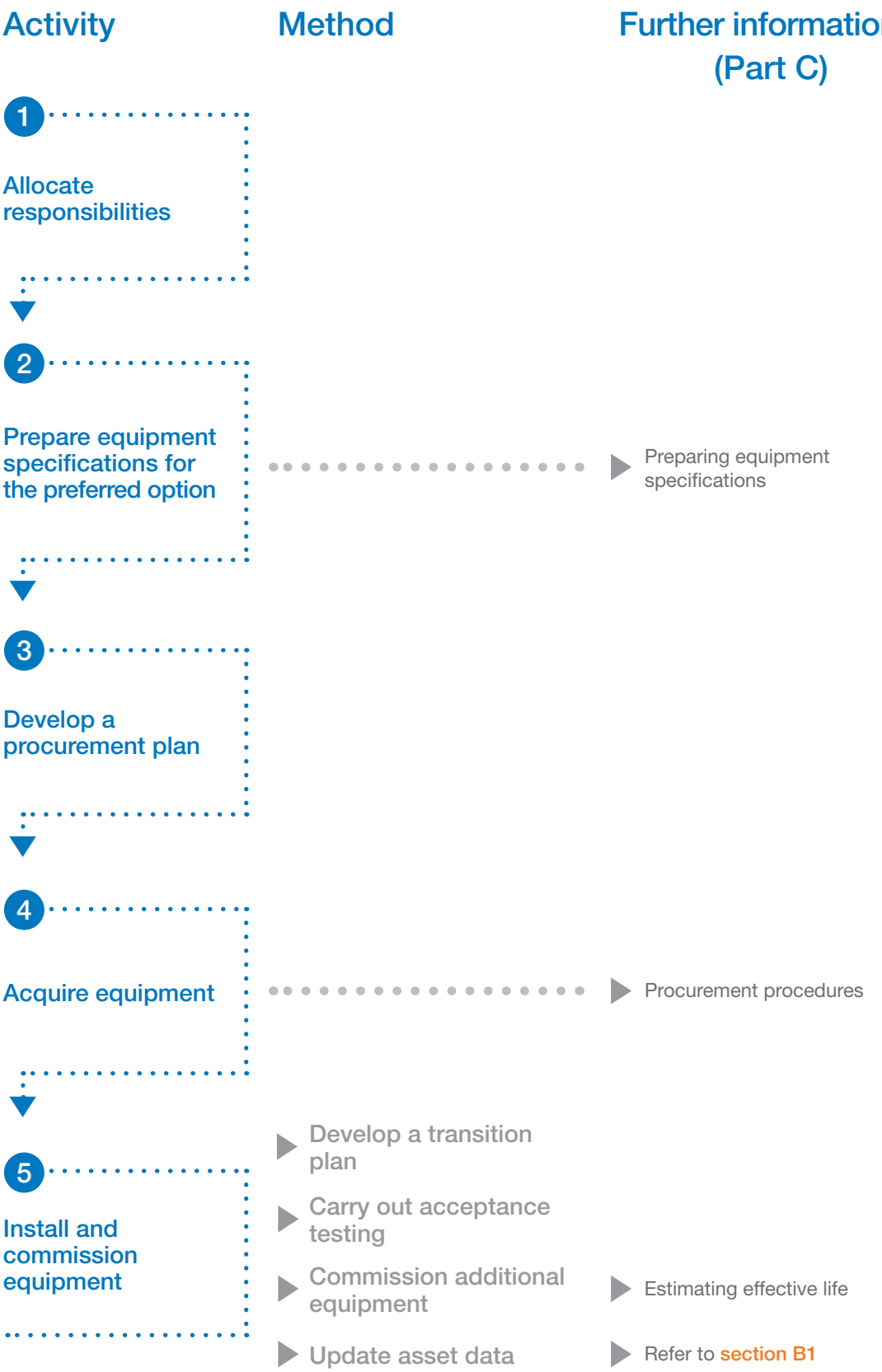
This section describes the acquiring of replacement or additional equipment once approval to proceed has been granted and funds have been allocated. The main activities are to:

- allocate responsibility for acquiring equipment
- finalise the preparation of equipment specifications for the preferred option
- develop a procurement plan
- acquire equipment
- install and commission equipment.

The activities may be adapted based on the type and complexity of the equipment being acquired.

Activity diagram 3 shows the steps needed to acquire equipment and the methods to be followed, and refers to the supporting information and tools available.

Activity diagram 3 — Acquire equipment



1

3.1 Allocate responsibilities

Responsibility for acquiring equipment lies with the health service that will use the equipment. Acquiring equipment will normally be undertaken by a specialist corporate services procurement unit.

The intended users of the equipment should be consulted during procurement (as with other stages of the lifecycle of the equipment), particularly on the specifications, selection criteria and the evaluation of offers.

2

3.2 Prepare equipment specifications for the preferred option

A specification must be clear and complete, and accurately define what is expected from a supplier, and be consistent with the acquisition plan developed in the planning phase.

Equipment specifications describe:

- the required qualities of the equipment to be acquired, including functional performance and other characteristics such as size, weight or energy consumption
- all the associated work involved in delivery and installation, including any necessary building works and services connections.

This may require more than one purchase order or contract.

Equipment specifications prepared must be:

- consistent with the attributes and specifications defined in the business case (or checklist) described in section B2
- capable of being satisfied by a competitive market, or where exemptions are made in compliance with government policies.

In particular, specifications should:

- define requirements
- neither underspecify nor overspecify requirements
- where possible, be written in terms of outputs or functions required, rather than listing technical requirements
- support standardisation and rationalisation

- not restrict competition
- not act as a barrier to introducing a new product or technology
- encourage tenderers to offer innovative options or solutions
- include a brief explanation of how this item will fit into the existing health service plan for delivering services
- include location and department area, descriptions of users, functions required, and connections or interaction with other medical equipment or systems.

Further detailed specifications may include:

- technical and operational requirements, such as
  - patient characteristics
  - physical characteristics
  - options and accessories
  - modes of operation
  - output values or ranges
  - critical performance characteristics
  - alarms
  - requirements for use
- environmental considerations, such as
  - environmental conditions
  - compliance with regulations and standards[1]
  - occupational health and safety
  - sustainability
- commercial considerations, such as
  - warranty and guarantee
  - user training
  - site preparation
  - installation
  - commissioning
  - ongoing maintenance.

✱ Refer to Part C
– 'Preparing equipment specifications'

✱ Refer to Part C
– 'Procurement procedures'

Specifications should align and be consistent with procurement policies, practices and arrangements that are required, with some classes of assets subject to acquisition within a set purchasing strategy by an authorised entity.

1 Australian Standard/New Zealand Standard (AS/NZS) 3551:2004 — *Technical management programs for medical devices*, Section 3.2.2.

3

3.3 Develop a procurement plan

Medical equipment acquisitions may be undertaken through a range of methods: procurement using centralised government agencies, joint arrangements with health services or other entities, or by individual hospital/health services.

The procurement plan must be consistent with the approved business case and implement the agreed business case.

Health services have a number of options for acquiring equipment including:

- outright purchase, using either department-sourced funds or non-department-sourced funds (the potential for disposal of the superseded equipment should be explored as part of the acquisition, along with possible proceeds from disposal)
- an operating lease
- a service contract with a third-party provider
- donations.

▶ **See also section B2** for further information on asset planning

In the case of potential donations, responsibilities for the funding and management of the operation and maintenance of the equipment must be clearly established. The preferred method of proceeding is then documented in the procurement plan.

The procurement plan must align with any specific purchasing arrangement government requires health services to enter into.

4

3.4 Acquire equipment

Procurement is strictly regulated to ensure probity, competition and value for money.

The following actions form part of procurement:

- Confirm the acquisition strategy as set out in the procurement plan.
- Finalise the equipment specification.
- Decide the procurement process (tender, expressions of interest, direct purchase).

- Define the selection criteria and weighting.
- Develop the tender response format, including the proposed form of contract with the supplier.
- Get a response from the market.
- Evaluate the bids and select the vendor.
- Obtain approvals and finalise the sign-off process.
- Issue the purchase contract or order.

✱ Refer to Part C – 'Procurement procedures'

The specific procedures to be followed depend on the price of the equipment, or where specific purchasing arrangements are required to be entered into. Some of these steps may be shortened or waived for minor or low-risk purchases at the discretion of the purchaser, but the relevant probity principles and policies must always be followed and comply with Victorian Government requirements.

5

3.5

Install and commission equipment

3.5.1 Develop a transition plan

As part of procurement, health services should develop a transition plan to ensure the continuation of service delivery while the replacement or additional equipment is brought into service. A period of temporary changes to service delivery may be needed to enable the equipment to be installed, tested and commissioned into service. This transition plan provides a basis for identifying risk management strategies to maintain clinical safety and implement contingency measures if there are delays in the equipment set up.

3.5.2 Install equipment

Responsibilities for installation should be clearly established in the purchase order or contract for the equipment.

Some fixed medical equipment requires installation before operation. In some cases, this involves installing connections for services such as electricity, water or drainage. In other cases, substantial building works are

required such as strengthening floors, improving air-conditioning or moving walls.

The scope of installation works required should be identified during the procurement process in consultation with the chosen supplier of equipment.[2] The installation of the equipment, together with any associated building works, should be coordinated with the supplier (if not completed by the supplier) to ensure the requirements for the equipment are met, and no contractual or warranty disputes result.

3.5.3 Carry out acceptance testing

Acceptance testing ensures the goods delivered are in accordance with the purchase contract and specifications, and that they are in a satisfactory condition (fit for purpose, undamaged). When there is no formal commissioning of the equipment, this stage may also involve testing some or all the goods to ensure they function as per specification and are safe to operate.

3.5.4 Commission equipment

Commissioning refers to the steps taken to put the equipment into service after installation and acceptance testing are complete. It includes:

- performance verification to ensure the equipment is capable of performing as intended by the manufacturer
- calibration or configuration before operation, usually done in consultation with the clinical users of the equipment
- development of operating routines (including operating manuals) and maintenance procedures
- staff training
- establishment of a regular procedure for assessing the fitness for purpose of the equipment for the periodic re-evaluation of effective life.

As soon as equipment is commissioned, the equipment superseded by the installation should be disposed of, and the asset data and information history updated.

3.5.5 Update asset data

The new equipment is now an asset to the user and full details must be recorded on the asset register and data information systems.

✱ Refer to Part C
– 'Estimating effective life'

▶ See also section B1.2.2
for further information about effective life

▶ See also section B5
for further information about disposal

▶ See also section B1
for further information on managing asset information

2 Australian Standard/New Zealand Standard (AS/NZS) 3551:2004 — *Technical management programs for medical devices*, Section 4.2.5.

Operate, maintain and monitor equipment

B 4

Overview

The operate, maintain and monitor stage is usually the longest in the asset management lifecycle. A consistent pattern of maintenance and monitoring throughout this stage is necessary to ensure each asset:

- delivers the required performance
- achieves its expected effective life
- minimises operating costs
- delivers maximum return on investment.

The aims of effective management of operation, monitoring and maintenance are to:

- maximise the effective life of the asset by developing and implementing carefully designed maintenance plans
- monitor performance by regularly assessing fitness for purpose, risk and expected effective life.

Activity diagram 4 shows the activities involved in achieving these aims and the methods to be followed, and refers to the supporting information and tools available.

Activity diagram 4 — Operate, maintain and monitor equipment

Activity	Method	Further information (Part C)
1 Allocate responsibilities		
2 Maximise the effective life of the asset	Develop and implement operating and maintenance plans	Maintenance tasks Maintenance guidelines Maintenance records
	Set up maintenance contracts as needed	Setting up maintenance contracts
3 Monitor performance	Assess fitness for purpose	Assessing fitness for purpose
	Assess risk	Assessing and rating risks
	Assess effective life	Estimating effective life
	Update asset data	Refer to section B1

4.1 Allocate responsibilities

It is the responsibility of health service managers to:

- establish a maintenance strategy for medical equipment
- delegate responsibility for the implementation of this strategy to suitably qualified people or organisations
- allocate sufficient resources to implement the maintenance strategy
- arrange for staff training.

Maintenance tasks can be carried out by:

- the supplier of the equipment
- a third-party maintenance provider
- in-house users
- appropriately qualified in-house specialist staff
- combinations of the above.

The decision about who will carry out maintenance tasks will be influenced by:[1]

- the type and number of items of equipment
- the cost and complexity of equipment
- the cost of maintenance options
- the availability of maintenance staff (both internal and external)
- the availability, cost and frequency of training, and special tools or software
- risk management (health service policies on mitigation of risk in combination with risk assessment of the equipment).

In some health services, a number of different maintenance groups might be responsible for different categories of medical equipment.

1 AS/NZS 3551:2004 — *Technical management programs for medical devices*, Standards Australia/Standards New Zealand (https://infostore.saiglobal.com/store/Details.aspx?ProductID=373238), Section 2.4; Nordic Committee on Accessibility 1998, *Nordic guidelines for computer accessibility* (http://trace.wisc.edu/docs/nordic_guidelines/nordic_guidelines.htm), Sections 7.5 and 12; DB 2006(05) Managing medical devices, Medical and Health Care Products Regulatory Agency, UK (www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON2025142), Sections 8.2 and 8.3.

4.2 Maximise the effective life of the asset

4.2.1 Develop and implement operating and maintenance plans

The users of an item of medical equipment need to specify the standards of reliability and performance that it can be realistically expected to maintain. The achievement of these standards influences the design of the high-level maintenance strategy (for example, the level of preventive maintenance). The maintenance strategy will identify inclusion criteria for items to be listed on the medical equipment inventory and delegate responsibility for maintenance of each item to appropriate personnel.

The maintenance strategy outlines the maintenance plans for each item in the inventory.

✱ Refer to Part C
– 'Maintenance tasks'

Maintenance plans contain maintenance tasks[2] (or work instructions), which outline the particular procedures that need to be carried out during the life of the equipment.

The maintenance requirements of specific items are determined by the original equipment manufacturer guidelines (as described in the service or maintenance manual) and Australian and New Zealand Standard (AS/NZS) 3551 — *Technical management programs for medical devices*.

✱ Refer to Part C
– 'Maintenance guidelines'

The range and timing of maintenance required for a specific item should be assessed by qualified personnel during acceptance testing.

Many items of medical equipment require initial calibration to establish the accuracy of measurements to be undertaken, and periodic recalibration to ensure standards are maintained. These checks are usually made by biomedical engineers and form part of routine maintenance.

▶ **See also section B3** for further information on acquiring equipment

Decisions as to who will perform each task, and when, should be made and recorded with the asset details when the equipment is acceptance tested.[3] The maintenance plan normally includes regular cleaning, lubrication (where appropriate) and the provision of any necessary consumables.

2 AS/NZS 3551:2004, Section 4; DB 2006(05), Section 8.2.

3 ibid.

The frequency of maintenance[4] should be determined by the manufacturer's guidelines, supplemented by operational experience. Any deviation from these guidelines should be supported by a formal risk assessment that demonstrates an acceptable level of residual risk.

A maintenance schedule lists the tasks required for each item, the due date for those tasks, and the person(s) responsible for performing each task.

★ Refer to Part C
– 'Maintenance records'

An essential part of any maintenance strategy is management of maintenance records,[5] which may include documentation of standards, manuals, procedures and contracts.

It is also important to track operating costs (which may include maintenance, energy use and cleaning) in order to:

- keep operating costs under control and at their lowest practical level
- verify that the operating costs estimated in the business case and lifecycle costing were realistic and can be achieved
- provide input into future lifecycle costing exercises for replacement or additional equipment.

4.2.2 Set up maintenance contracts

Any contractual agreement with a maintenance or repair service provider should specify the level and type of service required by the responsible organisation. Legal advice should be sought and technical acumen applied when drawing up contracts, including specialist advice when specific legislation covers the equipment, for example, the *Radiation Act 2005* (Vic) and the Radiation Regulations 2007 (Vic),[6] or the *Radiation Protection and Nuclear Safety Act 1998* (Cwlth),[7] *Safe Work Australia Act 2008* (Cwlth)[8] and *Occupational Health and Safety Act 2004* (Vic).[9]

★ Refer to Part C
– 'Setting up maintenance contracts'

4 AS/NZS 3551:2004, Section 4.4; DB 2006(05), Section 8.4; Canadian Medical Biological Engineering Society (CMBES) 2007, Clinical Engineering Standards of Practice for Canada, Section 3.2.4.2.

5 AS/NZS 3551:2004, Section 2.3.4; DB 2006(05), Section 2.2.1; CMBES 2007, Section 3.2.1; Nordic Committee on Accessibility 1998, Section 13.

6 www.health.vic.gov.au/environment/radiation/legislation.htm

7 www.arpansa.gov.au/regulation/legislation/index.cfm

8 www.comlaw.gov.au/Details/C2009A00084

9 www.worksafe.vic.gov.au/wps/wcm/connect/wsinternet/WorkSafe/HomeLaws+and+Regulations/Acts+and+Regulations/

4.3 Monitor performance

Regular monitoring activities include assessment of fitness for purpose, risk and effective life.

4.3.1 Assess fitness for purpose

A fitness-for-purpose assessment includes assessment of the following issues.

- Performance
  - Does the asset comply with relevant Australian and international standards?
  - Are the energy, maintenance and repair costs reasonable?
  - Are the operating costs higher or lower than those of comparable equipment?
- Condition
  - Is the equipment adequately maintained?
  - Can maintenance achieve the required condition?
  - Are major replacements or refurbishments likely to be required, and within what timeframe?
- Function and clinical efficacy
  - How well suited is the equipment to the services it supports?
  - What is the evidence-based efficacy of the proposed procedures? Is the equipment used for clinical purposes or research, or both?

The frequency and rigour of assessments should increase as the equipment approaches the end of its expected life.

Upgrades should be considered at each key decision point.

✱ Refer to Part C
– 'Assessing fitness for purpose'

▶ See also section B2.3.3 for further information about fitness for purpose

✱ Refer to Part C
– 'Key decision points in medical equipment asset management'

4.3.2 Assess risk

If the fitness-for-purpose or effective-life assessments reveal that the equipment is unsatisfactory against any of the components measured, a risk assessment should be conducted to determine whether the equipment poses any serious clinical risks to patient safety, occupational health and safety or service availability.

The risk assessment and rating of individual items of medical equipment should be part of the risk management program of each health service and should align with the overall risk management program and policy.

Medical equipment risk is measured by considering the adverse events that might occur when an item of medical equipment is used or when it fails to operate.

When to do a risk assessment

A risk assessment is usually required:

- on acceptance (delivery and commissioning)
- periodically throughout the life of the asset
- when the fitness for purpose of the equipment is assessed as below acceptable standards
- when a critical incident involves the asset.

When rating medical equipment, three critical risk categories are considered:

- clinical risk (patient safety)
- occupational health and safety risk
- service availability risk.

Risks should be ranked according to the likelihood of a serious event and the seriousness of the consequences. Services should assess how the delay in acquiring the replacement equipment would affect critical risk factors, how dependent the health service is on this item of medical equipment for service delivery, and what the possible flow-on implications are if the equipment is not available.

The results of the risk assessment are used to inform decisions about the equipment (repair, refurbish, replace, retire) and as an input into the asset planning process.

✱ Refer to Part C
– 'Assessing and rating risks'

▶ See also section B2
for further information about asset planning

4.3.3 Assess effective life

In some circumstances it may not be possible to reach the expected effective life (if, for example, the supplier is unable to continue providing spare parts or the equipment suffers a catastrophic failure). However, many assets may not require immediate replacement at the end of the estimated effective life.

Effective life assessment is required to determine whether the asset is reaching the end of its effective life and what future service potential could be obtained from the equipment (including opportunities for the disposal or re-allocation of the equipment).

If an item is functioning correctly, has been well maintained and is able to continue to reliably deliver and support the service requirements satisfactorily, there is often no need to replace it — all other factors being equal. However, the extensive use of ageing equipment puts more reliance on manufacturer support and increases the risk of equipment failure.

Specific maintenance strategies provide an opportunity to extend the effective life of assets. These include refurbishment, software upgrades, overhaul and redeployment to lower use areas. Health services are encouraged to employ these techniques to maximise the effective service life and the return on investment for these assets.

In some circumstances, it is outside the health service's capacity to ensure an asset meets its expected effective life, for example, if the supplier is unable to provide the required essential spare parts or if the device suffers unexpected catastrophic failure. If this happens, the health service should document why the asset did not reach its expected life, and provide a strategy for managing the resulting risks and subsequent replacement.

✱ Refer to Part C
– 'Estimating effective life'

▶ See also section B1.2.2 and section B2.3.3 for further information on effective life

Many assets will not require immediate replacement at the end of their expected effective life. Health services need to carry out regular fitness for purpose assessments of assets reaching the end of their effective life to determine the current risks and the strategy for replacing these assets.

4.3.4 Update asset data

All operating and performance monitoring data must be captured and recorded as asset data, either in real time or through regular updating procedures.

▶ **See also section B1**
for further information on maintaining asset information

The department relies on health services maintaining up-to-date data on performance, condition and function (including time series, key performance indicators and historical summaries). This information needs to be available on request to provide evidence for effective asset management and to support health service submissions.

Decommission and dispose of equipment

B5

Overview

When equipment reaches the end of its effective life or is replaced, it must be decommissioned and disposed of. Disposal must:

- safely remove equipment that is no longer suitable for use
- remove all patient information and health service labels or identifiers associating the asset with the particular health service
- ensure public health and safety by removing any health hazards associated with decommissioned equipment
- achieve maximum financial return to the government by maximising re-sale value or, at least, minimising disposal costs.

Effective management of decommissioning and disposal of equipment involves:

- allocation of responsibilities and definition of disposal procedures according to a disposal strategy
- decommissioning of the equipment
- disposal of equipment according to recognised standards and guidelines.

Activity diagram 5 shows the activities involved in achieving these aims and the methods to be followed, and refers to the supporting information and tools available.

Activity diagram 5 — Decommission and dispose of equipment

Activity	Method	Further information (Part C)
1 Allocate responsibilities		
2 Prepare disposal strategy		
3 Decommission equipment		
4 Dispose of equipment	▶ Choose the most appropriate means of disposal	▶ Medical equipment disposal
	▶ Ensure disposal procedures meet appropriate guidelines	
	▶ Update asset data	▶ Refer to section B1

5.1 Allocate responsibilities

Health services are responsible for the disposal of equipment under their control.

The disposal process should be initiated when:

- a replacement asset has been acquired and commissioned (in this case, disposal of the replaced asset should be automatic and mandatory)
- the asset has reached the end of its effective life
- the asset is no longer necessary to meet a service delivery requirement.

The disposal process may require the services of experts or contractors to undertake specialist tasks such as valuation, decontamination, the conduct of auctions and controlled dumping to landfill.

It is the responsibility of health services to:

- nominate staff to oversee the disposal process
- identify and communicate the preferred arrangements for disposals to relevant staff
- assess the need for specialist support services
- engage experts to develop contract terms and to assist in preparing contracts (particularly for complex and non-standard disposals) to minimise the exposure to risk
- select and enter into contracts with the providers of support services
- remove all patient information and health service labels or identifiers associating the asset with the particular health service
- provide clear instructions to those responsible for disposal
- monitor progress until the disposal process is complete
- document the disposal process.

5.2 Prepare disposal strategy

The decision to dispose is an intrinsic part of the decision to decommission or acquire replacement equipment and will normally be a part of the integrated planning process set out in section B2. The business case for the proposed replacement should outline the intended disposal strategy for the equipment to be replaced, including the method of disposal, the timetable for disposal, and the estimated disposal costs or returns. Commissioning of the replacement equipment will then trigger the disposal procedure described below.

▶ **See also section B2.5.1** for further information about preparing a business case

The decision to dispose can also arise outside the normal planning process as the result of a catastrophic failure that cannot be economically repaired, if the supplier is unable to continue providing spare parts or if there are unexpected changes in the service delivery requirement. In such circumstances, health services will need to develop the case for disposal, prepare a disposal strategy and evaluate the need to replace the equipment.

Health services need to make asset disposal decisions within an integrated service and financial planning framework. This includes evaluating the effectiveness of their redeployment or disposal strategies in maintaining an asset portfolio that best meets service needs, as well as establishing arrangements for the decommissioning of assets and for underperforming or surplus assets as efficiently as possible.

▶ **See also section B1** for further information about managing asset information

As part of a disposal strategy, health services should:

- establish and maintain an asset information system, that records all relevant information to assist in asset planning and management
- prepare and evaluate costings to support the selection of the most cost-effective disposal methods
- identify those areas most susceptible to risks, and introduce appropriate preventive measures
- monitor and evaluate disposal performance regularly for achievement, fair dealing, cost-effective choice of disposal methods, and compliance with the government's disposal policies and objectives.

3

5.3 Decommission equipment

Decommissioning is the permanent removal from active service of an item that has been replaced or is no longer required. Any item considered unfit for use should be decommissioned.

Decommissioning includes making the equipment safe to ensure any person who unintentionally uses it does not expose themselves to potential hazards.

Decommissioning involves:

- physically removing the equipment from the workplace
- decontaminating the equipment
- isolating or disabling the equipment so it cannot be mistakenly put back into service
- removing all labels associating the asset with the particular health service
- removing all patient information from items being disposed
- transferring equipment records from the active maintenance schedule and asset register into the archives.

4

5.4 Dispose of equipment

Disposal is the transfer of an asset to another location or owner so the asset is no longer the responsibility of the health service. Assets that have been decommissioned because they have reached the end of their useful life must not be put into storage, or transferred to other health services or government departments.

5.4.1 Choose the most appropriate means of disposal

Different disposal methods will be needed for different types of assets. Before deciding on a disposal method for a particular asset, health services need to consider:

- the nature of the asset, such as a specialised asset or a common item
- its ability to support other government programs
- the asset's life

- location (with respect to transportation or access)
- environmental considerations
- the number and size of assets
- its potential market value
- its trade-in value
- market conditions
- other intrinsic value of the asset.

Appropriate means of disposal may include any of the following methods.

Sale

The item may have residual value. This might be in the form of remaining clinical function or as scrap (through a scrap metal merchant). Sale can be via an expression of interest, public auction, public tender, sale to another entity or sale to staff. Before sale or transfer of ownership of medical devices, both parties should be clear about their legal liabilities. Legal advice should be sought if there is any doubt.

Trade-in

Including a trade-in provision in the contract is a straightforward way of ensuring the replaced assets are removed from a health service at minimal cost. The potential supplier of replacement equipment may offer a trade-in for the item or be encouraged to offer a competitive price on removal and disposal.

Donation

Some items might be suitable for use in other contexts, either locally or internationally.

Before donating medical devices, both parties should be clear about their legal liabilities.

Controlled dumping

✱ Refer to Part C
– 'Medical equipment disposal'

Items that have a low value or are unhygienic are usually disposed of by authorised dumping. This type of disposal usually goes to landfill and is carried out by commercial waste management companies.

Due diligence must be taken to ensure:

- such wastes are managed using the waste hierarchy to maximise resource recovery prior to disposal at landfill that is licensed to receive this category of waste
- the equipment is disabled and rendered safe so it represents no environmental, entrapment, radiation or electrical hazard, and becomes a solid, inert waste that can be taken to a landfill licensed to receive this category of waste
- hazardous or toxic components that might contaminate the landfill site are removed (for example, lead acid batteries, contaminated mineral oils, radioactive isotopes and mercury)
- any confidential stored information (for example, printed, hard disk or removable media) is either completely erased or the device is rendered physically unreadable to protect patient and institutional records.

5.4.2 Ensure disposal process meets appropriate guidelines

✱ Refer to Part C
– 'Medical equipment disposal'

The item that is being replaced must be disposed of in accordance with the appropriate guidelines and standards. Disposal must also take account of ethical and environmental responsibilities, and regulatory and legislated requirements.

5.4.3 Update asset data

▶ See also section B1.4
for further information on maintaining asset data

Records of equipment that has been disposed of should be archived. Basic information on performance and maintenance history should be kept to inform ongoing planning and management. Health services are required to report on the date of disposal of the item being replaced and update the asset register within the financial year in which the funding has been allocated to acquire the equipment.