Department of Health

health

Medical equipment asset management framework

Parts C – Tools

State Government Victoria

Medical equipment asset management framework

Part C – Tools

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About Part C

Part C presents technical and information resources ('tools') for medical equipment asset management. Its use will assist public health services to adopt a consistent approach to medical equipment asset management.

Part C will be updated or added to from time to time in the light of experience, advances or changes.

To ensure you have the most up-to-date Part C material, please visit www.health.vic.gov.au/med-equip to check the list of contents provided and access any changed material online.

Key to tools

I **Information sheets** provide more detailed information on some important issues required for medical equipment asset management.

T **Templates** can be completed at different stages of the medical equipment lifecycle.

P **Information packages** are self-contained information kits.

C **Checklists** cover requirements for some tasks.

L **Look-up tables** provide further information in tabular format.

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.

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C1.1 Standard nomenclature

Purpose	To describe the application of a preferred standard nomenclature system to an item of medical equipment.
Summary	The Global Medical Device Nomenclature (GMDN) is the preferred system for medical equipment in Victoria. This information sheet describes the GMDN and explains how the correct GMDN code is assigned.
Framework references	B1.2.1 – Use standard nomenclature

Version 1.0, 2011

I **Information sheet**

Standard nomenclature

Standard nomenclature must be used for medical equipment assets.

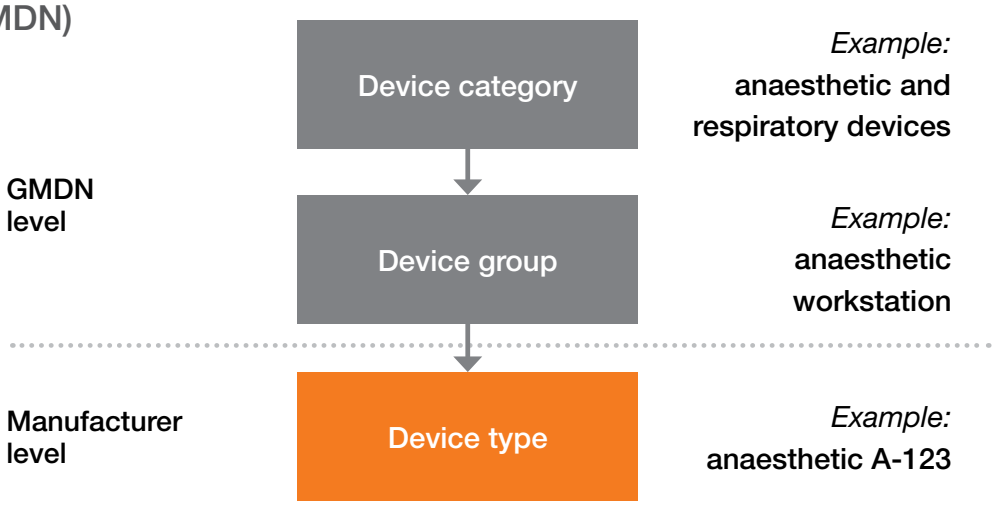
The Global Medical Device Nomenclature (GMDN) is a comprehensive system of internationally agreed coded descriptors used to identify medical device products. GMDN enables the standardised naming and categorisation of medical devices, accessories and systems, as well as other healthcare-related products (including technical aids, hospital and home care products). GMDN specifically includes the original coding given to the ECRI Institute's Universal Medical Device Nomenclature System (UMDNS) terms.[1] This enables the direct mapping of existing UMDNS-coded medical devices to GMDN coding where the UMDNS descriptor has been adopted unchanged in the GMDN.

> The main purpose of the GMDN is to provide authorities, healthcare providers, medical device manufacturers and suppliers, and regulatory bodies with a single naming system that will support patient safety.

The Therapeutic Goods Administration (TGA) in Australia is one of more than 20 regulatory bodies worldwide that have adopted GMDN. Others include the Food and Drug Administration (United States) and the Medicines and Healthcare products Regulation Agency (United Kingdom). GMDN is the only nomenclature system that can be used to officially identify medical devices within the European Economic Area.

TGA requires that the GMDN code be included as part of the registration of medical devices on the Australian Register of Therapeutic Goods (ARTG). Figure 1 shows the structure of GMDN.

Figure 1: Structure of the Global Medical Device Nomenclature (GMDN)



1 www.ecri.org/Products/Pages/UMDNS.aspx

GMDN aligns with the objectives of the Global Harmonisation Task Force for medical device regulation,[2] which include reducing duplication in regulatory systems and improving global trade opportunities while maintaining the quality and safety of medical devices.

How to apply GMDN to a medical device

If the exact equipment category is not listed, choose a GMDN device category that is closest in function, is used in the same area, or is used in the same or similar procedures to the equipment under consideration.

GMDN devices with their corresponding codes are available to Victorian public health services at www.health.vic.gov.au/med-equip

In those rare occasions that the GMDN category and code of the equipment in question cannot be identified, or its closest match is unable to be reliably sourced, seek further specialist advice.

This task would be undertaken by a specialist practitioner. The method of assigning the GMDN code to an item of medical equipment is to consult the online GMDN database. As codes and definitions are regularly modified, this is the most reliable method of assigning the correct code.

Alternatively:

- Search the ARTG[3] for the device under consideration and find the corresponding GMDN code and description. The ARTG has a publicly accessible listing of all devices approved for sale in Australia. Each device listing includes the GMDN category and code.
- Ask the equipment supplier for a copy of the ARTG registration to find the GMDN category and code. The equipment supplier is required to register or list all medical devices sold in Australia on the ARTG. The registration/listing application must include a device description that conforms with the GMDN.

2 www.ghtf.org

3 www.tga.gov.au/industry/artg-searching.htm/industry/artg-searching.htm

C1.2 Estimating effective life

Purpose	To define what effective life is, and how to estimate the effective life of medical equipment. Knowing the effective life of equipment shows the health service when the equipment may need to be replaced. This information sheet shows health services how to assess the effective life of their medical equipment so they can include this information in their equipment asset management plan.
Summary	This information sheet defines 'effective life' (in relation to other terms such as physical life and useful life) and describes the use of the 'MEAMF baseline' method of estimating it. An alternative engineering assessment may be undertaken if the baseline method is not possible or judged to be not appropriate. The associated template (C1.3) lists factors that can affect effective life.
Framework references	B1.2.2 — Measure effective life B2.3.3 — Identify equipment needs B3.5.4 — Commission equipment B4.3.3 — Assess effective life
Associated tools	C1.3 — Effective life baseline (L) C1.4 — Factors that influence the effective life of medical equipment (T)

Version 1.0, 2011

I Information sheet

Estimating effective life

The estimation of effective life, and its periodic reassessment, is a critical factor in planning for medical equipment. This information sheet defines effective life, relates it to other measures of life, and explains how the MEAMF baseline method is used.

Effective life is the period over which an item of medical equipment can provide the required clinical function or service for a health service. The Department of Health expects that an asset will complete its effective life before being considered for replacement. It is the responsibility of the health service to maintain equipment effectively to optimise its expected effective life.

Although the preferred term is effective life, other terms that are commonly used to refer to the period over which an item of equipment can provide a clinical service are:

- Physical life – the total expected number of productive years for an item of medical equipment. The physical life of an item of medical equipment has ended once it has physically deteriorated to an extent that it is no longer capable of being repaired or used for its intended purpose.
- Useful life – the period over which an item of medical equipment may be available for productive use by the health service or the number of units of use (for example, hours, procedures, exposures) expected to be achieved by the item of medical equipment by the health service.

Although they are not equivalent, these terms are often used interchangeably and may have different interpretations in different contexts.

Accounting depreciation

Depreciation rates can often act as a broad guide to estimating effective life. Equipment valuations include an adjustment for depreciation of each asset based on its age and the associated depreciation rate. The depreciation rate attributes the cost of acquisition over its effective life and it may be informed by advice from the Australian Taxation Office.

Tax ruling TR 2011/2 lists depreciation rates for a broad range of medical devices and provides a reference for health services to determine depreciation rates for medical equipment. Although the life of the equipment can be inferred from its recorded depreciation rate, it is not regarded as a primary source for determining MEAMF effective life.

Determination of effective life

The MEAMF baseline method provides the standard methodology to be used to estimate effective life.

Common criteria for determining effective life are technological obsolescence, followed by an item's fitness for purpose, maintenance, support and parts availability, legislation, the frequency of maintenance, use and cost.

The MEAMF baseline has been derived from the expected life of a specific asset achieved in both a major regional health service and a large metropolitan hospital with a high level of use for the equipment. The estimates were developed by testing equipment against industry benchmarks. The panel of biomedical engineers on the MEAMF Project Planning Team reviewed the assigned life of all assets for which the effective life varied by more than 20 per cent from other published effective lives for that category of equipment.

Factors that affect the effective life of an individual asset include:

- the frequency, environment and nature of use
- the care and attention paid to use and operator maintenance
- the existence, capability and cost of maintenance support
- the availability of consumables and spare parts
- the availability of upgrades and renewals
- changes in legislative and regulatory requirements
- changes in industry or professional standards
- variation between manufacturers
- poor manufacturing quality
- technological or clinical redundancies.

How to find the MEAMF effective life

The preferred method for determining the effective life of an item of medical equipment is the MEAMF baseline.

MEAMF effective life baseline

For commonly used items of medical equipment, the effective life is well established and understood. Specialists are able to assess with a high degree of confidence the effective life of an item of equipment, drawing on previous experience and knowledge.

The baseline tabulates the effective life for each common GMDN category of medical equipment, using an average value for all makes and models of that category.
To access the baseline, refer to the look-up table in C1.4 ('Effective life baseline').

Some variation may be expected between individual assets.

Steps

1. Determine the appropriate GMDN category for the asset. If the exact equipment category is not listed, choose a GMDN device category that is closest in function, is used in the same area, or is used in the same or similar procedures to the equipment under consideration.
2. Using the baseline table, look up the GMDN category and the corresponding effective life for that device category. In those very rare occasions that the GMDN category and code of the equipment in question cannot be identified, or its closest match is unable to be reliably sourced, seek further specialist advice.

Factors that can result in the effective life of the item being different to the MEAMF effective life baseline are shown in the template at C1.3 ('Factors that influence the effective life of medical equipment').

Further reading on measuring effective life

American Society Healthcare Engineering of the American Hospitals Association (ASHE)1996, *Life expectancy projection benchmarks*, ASHE, Chicago.

American Society for Healthcare Engineering of the American Hospital Association (ASHE) 1996, *Maintenance management for medical equipment*, ASHE, Chicago.

American Society of Anesthesiologists (ASA) 2004, *Guidelines for determining anaesthesia machine obsolescence*, ASA, Park Ridge, Illinois.

Audit Scotland 2001, *Equipped to care: managing medical equipment in the NHS Scotland*, Audit Scotland, Edinburgh.

Audit Scotland 2004, *Better equipped to care. Follow-up report on managing medical equipment*, Audit Scotland, Edinburgh.

Biomedical Engineering Advisory Group (BEAG) 2004, *Lifespan of medical devices,* BEAG, South Australia.

Certified Practising Accountants Australia 2009, *Members handbook, Australian Accounting Standard AASB 116 Property, plant and equipment*, CPA Australia, Melbourne.

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

Medical Imaging Advisory Group 2009, *Essential medical imaging equipment*, Medical Imaging Advisory Group, South Australia.

Monash University Centre for Biomedical Engineering 2007, *Independent review of medical equipment*, Monash University Centre for Biomedical Engineering, Melbourne.

National Health Services (NHS) 2006, *Capital accounting manual*, NHS, Edinburgh.

Redback Health Services 2009, *MEAMF independent review*, Redback Health Services, Melbourne.

Victorian Health Care Association Ltd 2005, *Health service capital expenditure and management review*, Victorian Health Care Association Ltd, Melbourne.

C1.3 Effective life baseline

Purpose	To provide baseline effective lives for medical equipment.
Summary	This look-up table tabulates the baseline effective life for each Global Medical Device Nomenclature (GMDN) category of commonly used medical equipment, using an average value for all makes and models of that category. The baseline look-up table is provided online to Victorian public health services at: www.health.vic.gov.au/med-equip
Framework references	B1.2.2 — Measure effective life B2.3.3 — Identify equipment needs B3.5.4 — Commission equipment B4.3.3 — Assess effective life
Associated tools	C1.2 — Estimating effective life C1.4 — Factors that influence the effective life of medical equipment

Version 1.0, 2011

L Look-up table

C1.4 Factors that influence the effective life of medical equipment

Purpose	The purpose is to provide a basis for estimating effective life when it is unable to be made using the MEAMF baseline. It is likely that this template will be used rarely and should be completed by individuals with the requisite specialist knowledge and experience. When used, it must be kept as part of the records of the equipment.
Summary	The template lists the factors that influence effective life. Specialists consider the factors that influence effective life and the impact of these on equipment. The effective life can then be calculated when it is unable to be determined using the MEAMF baseline.
Framework references	B1.2.2 — Measure effective life B2.3.3 — Identify equipment needs B3.5.4 — Commission equipment B4.3.3 — Assess effective life
Associated tools	C1.2 — Estimating effective life (I) C1.3 — Effective life baseline (L)
Version 1.0, 2011	

T Template

Factors that influence the effective life of medical items

Each factor in this template is considered for its potential change to the effective life of that item of equipment.

For example, consider factor 1 – Usage: What percentage impact does the actual usage of this item have on its effective life? If the item is used less intensively than normal, a possible answer is 10 per cent increase. Consider factor 7 – Obsolescence. Clinical practices may be changing, suggesting a possible reduction of 20 per cent.The net effect of these adjustments is then –10 per cent, resulting in an amended effective life of nine years for an asset with an effective life of 10 years.

Factor	Description	Impact on effective life
Physical life of medical equipment item	The physical life is considered the maximum achievable effective life. It is the total number of hours/years of expected use before deterioration. It is commonly based on the history of similar items or on professional standards set by, for example, the College of Biomedical Engineering (Engineers Australia) or the American Hospital Association.	
1. Usage	The nature, frequency and intensity of use will influence the effective life of an item of equipment. For example, a dialysis machine used for three shifts per day would be expected to have an effective life of 66 per cent of that for one being used for two shifts per day.	

Factor	Description	Impact on effective life
2. Physical environment	An optimal physical environment maximises the effective life of equipment. Where a suboptimal environment exists, the effective life is likely to be shortened. Environmental factors include temperature regulation, quality of power supply, and air and water quality. Also, some locations result in abuse and misuse of equipment, which has a detrimental effect on its effective life. This might occur in high-acuity areas like emergency departments or operating suites.	
3. Repairs and maintenance	Effective life can be maximised by regular maintenance and adherence to professional standards.	
4. Engineering information/ manufacturer's specifications	The life expectancy advised by the manufacturer is valid if the maintenance recommendations are followed. Training, regular maintenance and usage in accordance with the guidelines is critical to achieve the manufacturer's predicted lifespan for the item of equipment. Using the equipment outside the intended purpose can impact on life expectancy.	
5. Support	Effective life is affected by the level of support available from the supplier/ manufacturer. This includes sales support for consumables and accessories, availability of software and hardware upgrades, and availability of spare parts.	
6. Compatibility	Whether an item is compatible with other equipment in the department/area can impact on its effective life.	

Factor	Description	Impact on effective life
7. Obsolescence	This can arise for either (a) technological or (b) clinical reasons: (a) Technologically, a new more advanced version of the item may outperform its predecessor – time-wise, safety-wise and/or financially – rendering the predecessor obsolete, even though the equipment may still be functional. It should be noted that effective life does not end with each technological advance. (b) Clinical obsolescence may arise when medical practices or standards or treatments change, demanding the progression to another treatment type, rendering an item obsolete.	
8. Financial viability	The effective life of an item is reduced when the cost of delivering the service with the existing equipment is higher than if a different type of equipment were to be used. This might be because of the cost of consumables, lack of availability (hence revenue) due to reliability issues, or the maintenance/spare parts costs. The equipment might need more servicing because it has become unreliable, or spare parts might not be readily available.	
9. Legislative and regulatory requirements	Regulations can change over time, making some existing equipment non-compliant, for example, OHS regulations and the *Radiation Safety Act 1999*. Non-compliant devices represent a risk to health services, and some equipment may be replaced earlier than expected because of this. This can result in a shortened effective life.	

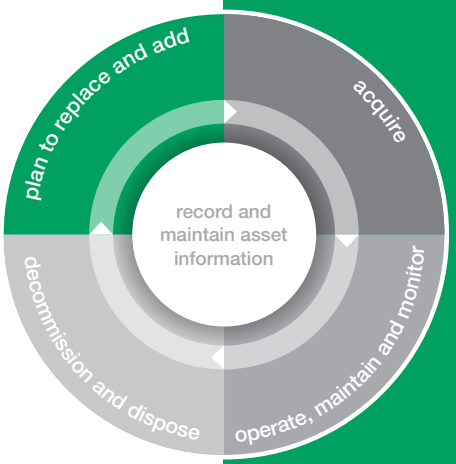
Factor	Description	Impact on effective life
10. Industry/college/ professional standards	In addition to legislative standards, the industry or profession may have its own standards, for example, professional accreditation, compatibility with existing equipment or minimum requirements for a specialist area within a practice.	
11. Retention period	The period over which a health service would normally hold the item can be shorter than its effective life. For example, some items are leased and the lease period is often shorter than the item's effective life.	
12. Decommissioning or retirement	Decommissioning and/or disposal usually marks the end of the effective life of an item of equipment. The exception is where an item is traded-in or sold, and will be used in a different location.	

OHS = occupational health and safety

C2.1 Assessing fitness for purpose

Purpose	To describe a structured approach to the assessment of the 'fitness for purpose' of an item of medical equipment.
Summary	The information sheet describes a rating system that takes into account performance, condition and function. The rating system suggests when corrective action needs to be taken and guides the nature of that action.
Framework references	B2.3.3 — Identify equipment needs B4.3.1 — Assess fitness for purpose
Version 1.0, 2011	

I Information sheet



Assessing fitness for purpose

Medical equipment is used for many critical tasks and the impact of failure can be life threatening or seriously affect services delivery. The fitness for purpose of the equipment must be monitored through its life to ensure it continues to meet acceptable standards for performance, condition and function.

If the equipment fails to meet the required standard in any of these areas, a review of its expected life, its maintenance plan and the continuing need for the asset is carried out to identify options for action (repair, refurbish, replace, retire). The review should be supported by a risk assessment. Section C4.3 describes how to assess and rate risk.

'Fitness for purpose' assessment

The 'fitness for purpose' assessment considers performance, condition and function. The three factors are assessed in a systematic rating procedure.

Relative 'fitness for purpose' rating system

A five-level rating system is used to rate each of the three elements relative to the 'required standard'[1] that is, performance required by the stakeholders for whom the asset is designed, used or required to be used, the type and level of condition, and the function.

The rating system uses a value between +2 and –2. A rating of '0' indicates the asset is at requirement. Positive ratings indicate the asset is above requirement, and negative values reflect below requirement.

The 'fitness for purpose' rating would be applied to the asset as a whole. If an accessory part or minor component is broken, this should be noted, but would not, by itself, determine the overall rating of the asset. For example, if the wheels of a bed are corroded, it does not necessarily result in a condition assessment of '–1' or '–2' unless the condition of the rest of the bed is in similar poor condition. Detailed descriptions of each of these rating elements are shown in Tables 1–3.

1 **ISO 1568:2010** Building and constructed assets – service life planning – Part 10 When to assess functional performance. Definition of functional performance requirement, International Organization for Standardization (http://infostore.saiglobal.com/store/Details.aspx?ProductID=1409417).

Performance

This covers:

- throughput and reliability
- compliance with relevant, current Australian and international standards, and clinical standards set by professional colleges or institutions
- the costs of operating the equipment, such as consumables and maintenance.

Table 1: Relative 'fitness for purpose' index — performance

Rating	Description	Indicative characteristics
+2	Well above required performance	Reliability of the asset does not affect service delivery Is fully compliant with all relevant statutory and other requirements, including Therapeutic Goods Administration (TGA), Standards Australia, WorkSafe Victoria and codes of practice of professional colleges
+1	Above required performance	Reliability of the asset does not affect service delivery Is compliant with significantly relevant statutory and other requirements, including TGA, Standards Australia, WorkSafe Victoria and codes of practice of professional colleges, with only minor exceptions in non-critical areas Cost of service delivery is not affected by consumable and maintenance costs
0	At required performance	Reliability of the asset does not affect service delivery Some expenditure may be required to maintain compliance and reliability Meets an acceptable level of compliance with relevant statutory and other requirements, including TGA, Standards Australia, WorkSafe Victoria and codes of practice of professional colleges Cost of service delivery is not significantly affected by consumable and maintenance costs

Rating	Description	Indicative characteristics
–1	Below required performance	Unreliability of the asset affects service delivery Fails to meet a number of statutory and other requirements for its current use Moderate refurbishment/enhancement is required to achieve the minimum standard Cost of service delivery is affected by consumable and maintenance costs
–2	Well below required performance	Unreliability of the asset significantly affects service delivery Has a number of significant non-compliances in critical areas and requires major refurbishment/ enhancement or replacement to achieve the minimum acceptable standard Cost of service delivery is significantly affected by consumable and maintenance costs

Condition

This assesses the external and internal state of repair including:

- worn mechanical components
- missing and broken parts
- corrosion
- the state of the finishes, such as painted surfaces or upholstery.

Table 2: Relative 'fitness for purpose' index — condition

Rating	Description	Indicative characteristics
+2	Well above required condition	Finished surfaces are unmarked No material wear in mechanical components No broken parts or material defects
+1	Above required condition	Defects in finish are only cosmetic in nature and do not affect service delivery or longevity Minor wear and tear is evident but does not affect service delivery
0	At required condition	The physical state of the asset meets the required standard Some deterioration may be evident Some routine service may be required to address wear and tear
–1	Below required condition	Defects in finish affect longevity or present an unacceptable hazard Wear and tear of mechanical components affect service delivery or present an unacceptable hazard Broken parts or material defects impair service delivery or present an unacceptable hazard
–2	Well below required condition	Defects in finish significantly affect longevity or present an unacceptable hazard Wear of mechanical parts significantly affect service delivery or present an unacceptable hazard Overall many defects are well beyond any reasonable level of acceptability

Function

This assesses the capacity of the equipment to deliver the required clinical diagnosis or treatment and includes the:

- quality of diagnosis or treatment
- safety of diagnosis or treatment
- range of diagnostic or treatment options.

Table 3: Relative 'fitness for purpose' index — function

Rating	Description	Indicative characteristics
+2	Well above required function	Performs all functions required for current service delivery Exceeds functionality requirements in some key areas Quality or precision of diagnosis/treatment greatly exceeds requirements for current service delivery
+1	Above required function	Performs all functions required for current service delivery Exceeds functionality requirements in some areas Quality or precision of diagnosis/treatment exceeds requirements for current service delivery
0	At required function	Performs all functions required for current service delivery Quality or precision of diagnosis/treatment meets requirements for current service delivery
–1	Below required function	Does not perform all functions required for current service delivery Quality or precision of diagnosis/treatment does not meet some requirements for current service delivery
–2	Well below required function	Does not perform all functions required for current service delivery Quality or precision of diagnosis/treatment does not meet requirements for current service delivery Lack of functionality/quality/precision is significantly affecting service delivery

A score of –1 or –2 in any of the three fitness-for-purpose elements (performance, condition, function) indicates the need for action to:

- restore the asset to an acceptable standard
- initiate maintenance/refurbishment/enhancement
- retire the item
- replace the item.

The action that is chosen will depend on, among other factors:

- the type of equipment
- the nature of the non compliance with the acceptable standard
- the availability of spare parts or an upgrade via hardware or software
- the ongoing need for the asset and whether alternatives or backups are available
- the age of the equipment compared with its MEAMF effective life baseline
- the cost of refurbishment/enhancement compared with replacement price.

At the conclusion of any action (other than replacement), a new fitness-for-purpose assessment is required to assess whether the action has resulted in the asset meeting the minimum acceptable level. If the asset meets the minimum acceptable level, it can be returned to service.

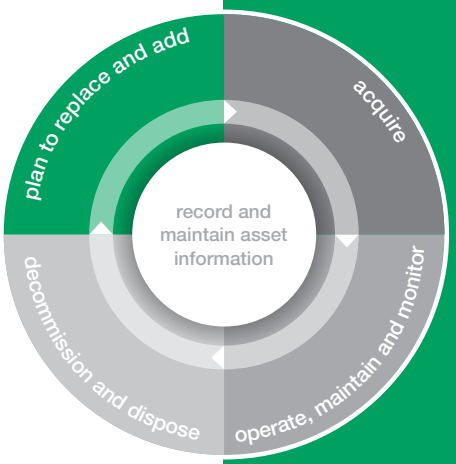
If the asset still fails to meet an acceptable standard after all reasonable actions (considering the remaining effective life) have been carried out, then a risk assessment would be performed (see section C4.3.2). This will identify the risks that need to be managed while the asset is considered for replacement/retirement. In certain cases, where the identified risks are significant, an asset will need to be removed from service, pending replacement.

C2.2 Requirement for a business case

Purpose	To describe when a full business case is required to support a proposed acquisition.
Summary	This information sheet lists the current thresholds for the preparation of full business cases.
Framework references	B2.5 — Prepare funding submission for preferred solution

Version 1.0, 2011

I Information sheet



Requirement for a business case

Business case templates will be used for submissions to the department either:

- when requesting capital funding for additional (versus replacement) equipment with a value in excess of $100,000
- when seeking permission for leasing[1] medical equipment
- when requesting capital funding for replacement equipment (individual items, aggregates or systems) with a value in excess of $600,000, or
- as requested by the department.

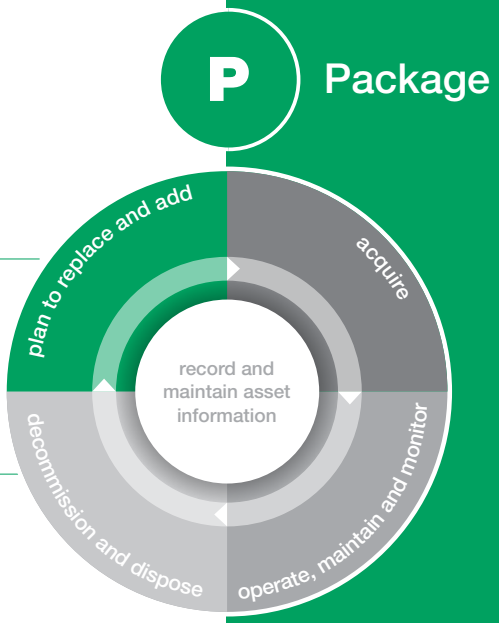
The above thresholds are current as of August 2011.

Business case templates may be used within a health service to assist in their equipment decisions.

1 Applies to both finance and operating leases. The approval requirements for finance leases are outlined in the *Borrowing guidelines for public hospitals and community health centres* (www.health.vic.gov.au/borrowing). The policy framework for entering into operating leases is set out in the *Prudential risk management framework for the state's financial markets' activities* (Department of Treasury and Finance, March 2001). In section 6.2.6, the *Prudential risk management framework* states, 'While there are no restrictions on operating leases, a financial evaluation must be performed on all operating leases greater than 12 months and for capital value worth more than one million dollars, to assess the cost of the proposal (refer Appendix 1 [of the *Prudential risk management framework*])'.

C2.3 Business case package

Purpose	To provide instructions for preparing a full business case.
Summary	The package includes the requirements of a business case and the method of preparing it. The package includes three components: **I** – Guidelines for preparing a business case **II** – Instructions for completing a full lifecycle costing template **III** – Instructions for completing a business case template The most up-to-date version of the full lifecycle costing template and the business case template will be sent to health service CEOs on request.
Framework references	B2.3.3 — Identify equipment needs B2.4 — Identify possible solutions (non-asset and asset) B2.5.1 — Prepare a full business case
Associated tools	C2.2 — Requirement for a business case C2.4 — Checklist for use when a business case is not required
Version 1.0, 2011	



Business case package

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Introduction

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This package includes the following components.

I **Guidelines for preparing a business case**

II **Instructions for completing a full lifecycle costing template**

III **Instructions for completing a business case template**

This package assists health services in preparing a business case to acquire or replace medical equipment. It is a guide to the extent and type of information that should be presented in developing a business case. Health services may find it necessary to augment the template with additional essential information and evidence where necessary to support the business case.

Purpose of the business case

A business case is a management tool that supports planning and decision making. It succinctly provides all relevant detail to enable an informed decision regarding the justification for seeking funding to acquire the requested medical equipment item or system, or future planning for replacement.

A medical equipment item or system business case explains:

- what the medical equipment item or system is
- why the medical equipment item or system should be acquired
- what outcome(s) will be achieved, such as improved throughput or reduced Occupational Health and Safety (OHS) risk
- what other options have been considered
- how much the medical equipment or system will cost over its effective life
- what the risks are and how these will be managed
- what the state of readiness is to implement the recommended option
- what the total amount of funding required is and the intended funding source.

When is a business case required?

It is intended that the completed business case templates will be used for submissions to the department either:

- when requesting capital funding for additional (versus replacement) equipment with a value in excess of $100,000
- when seeking permission for leasing medical equipment
- when requesting capital funding for replacement equipment (individual items, aggregates or systems) with a value in excess of $600,000, or
- as requested by the department.

These thresholds are effective as of August 2011.

Acknowledgements

The following documents were reviewed in developing this business case template:

- Department of Health, *Targeted equipment program 2005–06*, *Equipment submission form*
- Department of Health, *Business case template*, Version 0.1, 22 July 2004
- Department of Treasury and Finance (Victoria), *Gateway initiative, business case development* guidelines, revised April 2005
- Department of Treasury and Finance (Victoria), *Investment evaluation policy and guidelines*, September 1996
- Department of Treasury and Finance (Victoria), *Investment lifecycle guidelines*, July 2008
- Department of Health (Western Australia), *Business case guidelines*, October 2006
- statements of priorities (various health services).

I – Guidelines for preparing a business case

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This business case package provides instructions for the content of each section of the business case.

Preparing an executive summary

The executive summary will be used as a stand-alone companion document to the full business case document. It will cover all the key issues that a decision-maker will need to know about the proposed acquisition.

The executive summary would enable the reader to quickly gain an understanding of the:

- proposed acquisition
- options and alternatives considered
- analysis undertaken
- details of the preferred option
- implementation approach
- known key risks.

Although the executive summary is at the beginning of the business case, it is often the last prepared.

The executive summary will provide a succinct summary of the following key points:

- how the equipment or system will meet the identified service need
- alignment of the acquisition to the service objectives of the health service, as well as Department of Health and whole-of-government strategic directions
- the options considered for meeting the service need
- the short-listed options and the basis for the short listing
- the rationale for the preferred option, based on fitness for purpose, costs, benefits and risks
- readiness to implement and timeframes for implementation
- the lifecycle costs associated with the preferred option
- the budgetary implications for the acquisition – both capital and recurrent – and how it will be funded
- planning for implementation, including project management and governance, procurement strategy, post-implementation assessment and project risk management.

As a guide, the executive summary should be limited to one page for small, low-value medical equipment acquisitions, and a maximum of four pages for more complex, larger value proposals.

Description of medical equipment needs

Asset planning is fundamental to effectively managing an organisation. Matching the medical equipment requirements of health services to their service delivery strategy will result in medical equipment assets consistent with the scope, capacity and performance of the service required.

Planning and identifying needs is the starting point for asset management. This involves a thorough examination of why the particular equipment is required and must give consideration to the full range of options for responding to it. These options may include both non-asset and asset-based solutions, as well as demand management strategies. For example, if a health service has multiple ultrasound units in the health service, hospital or department, the needs analysis would clearly identify why a replacement or additional ultrasound may be required.

It is acknowledged that the decision-making process on equipment needs may occur in isolation to any funding opportunities or calls for funding submissions. The process of asset planning and identification of equipment needs enables the development of priority equipment needs. These priorities would be regularly reviewed and may require an update to reflect, for example, impacts from changes in technology, service delivery methods or the cost of equipment.

Introduction

The introduction provides a brief summary of the medical equipment acquisition proposal, and additional information on the proposal that may not be included in other sections of the business case.

This section may also be used to provide more detail on complex or high-value proposals, or those that have a longer or staged development history.

Strategic context

The purpose of this section of the business case is to clearly identify the strategic context for the proposed purchase and its linkage to the health service's strategic plans, departmental and whole-of-government priorities.

This section describes the strategic context in which the health service operates. Reference will be made, where appropriate, to the following:

- medical equipment asset management plans for the department and the health service
- health service strategic plan
- statements of priorities
- service plans
- regulatory and legislative compliance requirements, such as the *Radiation Safety Act 1999*.

The preceding list is not expected to be exhaustive but merely a guide to the nature and type of documents that would be referred to.

This section also articulates the link to the relevant documents and how the proposed acquisition aligns with the strategic directions for service delivery, and how the proposal contributes to the achievement of these policy directions, frameworks and strategies.

It is not necessary to re-state the relevant policy and strategy documents; instead, make a reference to the section or recommendation relevant to the proposal.

The strategic linkages and alignments are best presented in tabular form. The following table would be completed in preparing the business case.

The alignment of the proposed acquisition with the strategic directions of the government, department and health service is demonstrated by examples similar to those given below.

Policy statement/ strategic objective	Degree of alignment (high/ medium/low)	Evidence supporting degree of alignment
Example: Provide efficient and effective services based on evidence and need	High	Demand for services has increased by X per cent during the past two years. The purchase of this equipment will provide sufficient capacity to meet current and known projected future demand for the next Y years
Example: Achieve a financially sustainable organisation	High	The purchase of the replacement equipment will reduce ongoing maintenance and consumables costs by Y per cent per year, or a savings of $Z per year

Note: example table only

Where possible, the supporting evidence presented in the above table would be based on actual figures rather than estimates.

Service profile

This section of the business case provides the decision-maker with information on the current service and equipment, current and future demands on the service or department/area, as well as any changes to the nature, type and amount of equipment that may be required to meet those future demands.

Current service profile

This outlines the current operating environment of the specific service area/department relevant to the proposed equipment acquisition. It would include information on activity levels, demand, usage, patient profiles, types of procedures and waiting times to access the equipment. Also, more broadly, it would include details about the relative importance of the service area/department to the health service and the delivery of health services.

The following information, where relevant, would be included in the current service profile:

- types of services/procedures provided
- number of services/procedures provided
- service capacity
- waiting times for procedures
- patient profile and mix (public, private)
- service demand, usage, burden of disease
- fitness for purpose, use and effectiveness of equipment (capacity to sustain service delivery)
- relationships with other service providers and models of care.

Future service profile

This identifies how the service profile of the specific service area/department is expected to change, and the range of factors that would impact on the demand for and provision of these services over the next one to five years. These factors may include:

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

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A description of the future needs and demands for the specific service area/ department and the projected future levels of service provision would be provided. These future needs would be based on a short to medium-term horizon (one to five years). As a guide, the following information, where relevant, would be presented:

- projected impact of policies and strategies on the delivery of health services and models of care
- projected service demand and usage trends
- estimated service/procedure capacity requirements
- types of services/procedures to be provided
- projected activity levels by service type/procedure
- workforce requirements.

The assumptions underlying each projection must be explicitly stated.

Identified service need

The 'Current service profile' and 'Future service profile' outline the current and expected future service profile. This section would demonstrate the gap between the current level of service provided and what is required in the future.

The purpose of this section is to outline how these identified gaps could be overcome through the proposed equipment acquisition.

Indicators of current and future service profile

The following table includes examples of indictors that should be used to demonstrate how the service profile will change and are to be included as part of a business case.

It is important that the indicators chosen can be reliably and readily measured, and are relevant to the proposed equipment acquisition.

Service profile indicators	Current	KPI/evidence to support current profile	Future	KPI/evidence to support future profile
Patient profile				
Public/private prioritisation				
Compensable patients				
Revenue generation capacity				
Range of services/procedures provided				
Demand for the service/ procedure(s)				
Number of procedures performed by the medical equipment being acquired				
Waiting period for the procedure				
Frequency of accreditation/ certification requirements for the equipment being acquired				
Workforce requirements (number and type) relevant to the equipment acquisition				

KPI = key performance indicator

Note: example table only

In addition to anticipated changes to the future delivery of health services, the equipment needs would also be based on an understanding of the fitness for purpose of the existing medical equipment.

A review of the existing equipment will assist in determining whether the performance of these assets is adequate to support the service delivery strategy or if the equipment is no longer required, or superseded by changes in technology or changes in clinical practice.

In evaluating and reviewing equipment fitness for purpose, the following provides examples of some of the aspects that need to be assessed:

- *Importance* – How important or critical is the medical equipment to the health service? How does this equipment support the clinical service?
- *Condition* – Is the equipment adequately maintained? Can maintenance achieve the required condition? Are major replacements or refurbishments likely to be required in the short term (one to five years)?
- *Age/effective life* – Is the current asset reaching the end of its effective life? What future service potential could be obtained from the equipment?
- *Functionality/clinical efficacy* – How well suited is the equipment to the services it supports? What is the evidence-based efficacy of the procedures that are proposed to be undertaken? Which procedures are research related and how will they be funded?
- *Critical risk assessment* – Does the equipment currently pose any serious risks, such as clinical risk (patient safety), OHS or service availability risks? How would a delay in acquiring the replacement equipment affect critical risk factors? How dependent is the health service on this item of medical equipment for service delivery? What are the possible flow-on implications if the equipment is not available?
- *Usage* – How often and how intensively is the asset used? What is the actual usage compared with throughput capacity? What are the waiting times to use the equipment? What is the level of 'down-time' for the equipment compared with the manufacturer's benchmarks?
- *Costs* – Are the equipment's operating costs higher/lower than for those of comparable equipment? Are the energy, maintenance and repair costs reasonable?
- *Disposal* – What opportunities are there for the disposal or re-allocation of the equipment?

It is expected that this analysis would be facilitated by data captured in the health service's asset register and asset management systems.

Options evaluation

This section outlines the process used to develop and evaluate options to address the identified equipment needs and document the outcome of the evaluation. The business case briefly and succinctly describes the process followed in generating, assessing and comparing the options, and why the preferred option was chosen.

Summary of options

This section provides a summary list of the short-listed options and a brief description of each option.

Options development

Once the equipment need has been identified and articulated, the next step in the business case process is to consider the wide range of options for meeting the identified need. The range of options to be considered will also include non-asset solutions.

Possible options for consideration include:

- *non-replacement* – maintain the existing equipment item
- *replacement* – 'like-for-like' replacement of the existing equipment, noting that technological advances may have resulted in the replacement item being significantly different to the item being replaced
- *refurbishment/upgrade* – undertake upgrade works to the existing medical equipment item
- *consolidation/reconfiguration of existing equipment* – improve the usage rate of similar types of equipment to avoid the replacement or purchase of additional equipment
- *alternate service delivery* – investigate how the service could be delivered without investment in the new/replacement item of equipment, such as using an alternate campus or external service provider.

In developing the options for analysis, consideration would also be given to the possible funding options. These would include considering outright capital purchase, operating leases, outsourcing and 'bundling' the equipment acquisition with a consumables contract.

It is expected that the 'do nothing' option of maintaining the current service delivery arrangements will always be included as one of the options to be considered. This provides a base case for comparing the costs and benefits of the alternative options.

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Process for options development

This section briefly explains the process for identifying the possible options for meeting the identified equipment need.

Depending on the number and extent of options identified, criteria used for the short-listing of options should be documented in this part of the business case. It may be necessary to short-list the options for full analysis, with the remaining options summarised in an appendix.

Options analysis

The benefits and costs of each of the short-listed options needs to be analysed to identify the preferred option for meeting the service need. The analysis needs to cover both financial and qualitative considerations in order to determine the option that best meets the service need from an overall 'value-for-money' perspective.

Qualitative analysis

The qualitative analysis involves an assessment of the non-financial aspects of each short-listed option. This section of the business case documents the non-financial aspects of each option and assesses them against a set of evaluation criteria. The evaluation criteria could include but is not limited to the following:

- quality of healthcare (shorter stays, faster recoveries, less invasive procedures)
- safety (for staff and patients)
- usage (access to equipment, waiting times, throughput)
- fitness for purpose (alignment to service delivery strategy)
- integration/interfacing (that is, how well the chosen option can be integrated with other systems and equipment such as information technology (IT) and infrastructure already installed in the health service)
- change management impact (training, industrial relations)
- readiness to implement
- interdependencies and linkages to other projects.

The above criteria is not intended to be an exhaustive list; it is provided as an indicative set of criteria for evaluating and analysing each short-listed option. Consultation with key stakeholders can assist in developing additional criteria for evaluating short-listed options.

It is suggested that, in evaluating the satisfaction of each criteria, a scoring range of –4 to +4 be adopted, in accordance with the Victorian Department of Treasury and Finance (DTF) investment evaluation policy and guidelines, and as outlined in the table over the page.

Ratings	Value
Very much better than the base case	+4
Much better than the base case	+3
Moderately better than the base case	+2
Little better than the base case	+1
Same as the base case	0
Little worse than the base case	–1
Moderately worse than the base case	–2
Much worse than the base case	–3
Very much worse than the base case	–4

To enable the comparison of each option, it is recommended that the benefit evaluation is presented in a tabular form as follows.

Evaluation criteria	Base case ('do nothing' option)	Option 1	Option 2	Option 3
Example: Waiting time for procedures	0	–1	+2	+4
Example: Training requirements	0	0	–2	–1
Example: Readiness to implement	0	0	+1	+1
Total score	**0**	**–1**	**+1**	**+4**
Average score	**0**	**–0.33**	**+0.33**	**+1.33**

Note: example table only

The table above assumes that each evaluation criteria has equal weighting; however, there is no requirement to apply equal weightings to each evaluation criteria. The rationale for changes in weighting should be clearly explained in the business case.

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Financial analysis

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.

A full lifecycle cost analysis of the 'do nothing' option will be included as the base case. This will provide the baseline cost position, and will identify which options include significant changes in costs and will assist in identifying the required funding strategy.

The financial evaluation of each option would be conducted using the 'Lifecycle costing template'. The section includes instructions on how to use the template and provides guidance on the costs to include in the analysis over the expected life of the project. The reason for the chosen term (such as five years, seven years or 10 years) and any other key assumptions would be documented.

A summary table of the lifecycle cost analysis should be included in this section as follows.

Evaluation criteria	Base case ('do nothing' option)	Option 1	Option 2	Option 3
Revenues	($300,000)	($330,000)	($320,000)	($300,000)
Residual value	($5,000)	($10,000)	($8,000)	$0
Total revenue	**($305,000)**	**($340,000)**	**($328,000)**	**($300,000)**
Acquisition costs	$0	$250,000	$200,000	$0
Leasing costs	$0	$0	$0	$270,000
Maintenance costs	$300,000	$100,000	$100,000	$75,000
Repair costs	$65,000	$50,000	$50,000	$45,000
Operating costs	$75,000	$35,000	$40,000	$65,000
Disposal costs	$10,000	$7,500	$7,500	$2,500
Total costs	**$450,000**	**$442,500**	**$397,500**	**$457,500**
Total net lifecycle costs (net present cost)	**$145,000**	**$102,500**	**$69,500**	**$157,500**
Score	**0**	**+2**	**+4**	**–4**

Note: example table only

The table above shows hypothetical amounts for illustrative purposes only.

The financial analysis would be scored using the following rating system.

Ratings	Value
Least expensive compared with the base case	+4
Significantly less expensive than the base case	+3
Moderately less expensive than the base case	+2
Less expensive than the base case	+1
Same as the base case	0
More expensive than the base case	–1
Moderately more expensive than the base case	–2
Significantly more expensive than the base case	–3
Most expensive compared with the base case	–4

The detailed lifecycle cost analysis should be included as an attachment to the business case.

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Overall analysis

The qualitative and financial analyses provide commentary on the overall scores of the various options.

The example below assumes that the qualitative criteria has a weighting of 70 per cent and the financial criteria has a weighting of 30 per cent for determining the overall score for each option; however, different weightings may be applied in determining the combined weighted score.

The relative importance of financial impacts and qualitative criteria will depend on the strategic importance of the medical equipment, and the overall investment objectives for service delivery and financial performance. In the context of the overall options evaluation of medical equipment acquisitions, qualitative criteria will generally be given a higher weighting than financial performance.

Determining the relative weighting of financial impacts to qualitative criteria will be influenced by the service delivery objectives (such as health service strategic plans) and the financial performance outcomes expected from the investment in the medical equipment. The following table, based on DTF investment evaluation policy and guidelines, sets out some possible weightings based on different investment objectives.

Weightings

	Base case ('do nothing' option)	Option 1	Option 2	Option 3
Qualitative analysis	0	–0.33	+0.33	+1.33
Weighted qualitative analysis score (70%)	**0**	**–0.23**	**+0.23**	**+0.93**
Financial analysis	0	+2	+4	–4
Weighted financial analysis score (30%)	**0**	**+0.60**	**+1.20**	**–1.20**
Combined weighted score	**0**	**+0.37**	**+1.43**	**–0.27**

Note: example table only

Investment type	Non-revenue generating	Revenue generating	Commercial
Investment objective	Service delivery	Service delivery with some financial returns to offset operating costs	Service delivery and a commercial return
Qualitative analysis weighting	60–75%	50%	40–25%
Financial analysis weighting	40–25%	50%	60–75%

Note: example table only

Preferred option

The preferred option is determined by comparing the benefits derived by a specific option with its lifecycle cost (net present cost terms) from the overall option analysis.

The business case documents the preferred option and the reasons in terms of its cost and benefits. The rationale for the chosen option would be clearly stated and supported by the outcomes of the analysis. For example, reasons for selecting the chosen option could include:

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

In addition, how the preferred option aligns with the service objectives of the health service, the department and whole-of-government strategic directions.

Stakeholder support for the preferred option would be described in the business case. It should include details on which particular stakeholders have been consulted (such as area/department, title/role) and how these stakeholders have been involved in the development of the business case.

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Implementing the preferred option

This section of the business case outlines the intended approach to implementing the preferred option.

The project management arrangements and implementation plan have already been outlined in the business case. Although it is not expected that all elements of the implementation plan will have been determined or developed in detail at this point, the business case will outline the crucial elements of the implementation plan and how these will be addressed.

The following sections outline the type of information on the preferred option, and the project management and implementation that would be included in the business case.

Project management and implementation

The project management arrangements and plan for implementation of the preferred option are to be documented in the business case.

In most instances, implementation plans and strategies are unlikely to be fully developed at the time of preparing the business case. However, it is important that the business case demonstrates that the various issues and risk factors associated with the successful implementation of a project have been considered, and that strategies addressing these issues and risks are being developed.

Project management and governance

This section of the business case provides an outline of the project management and governance arrangements that have been used, or are in the process of being used, to manage the implementation of the proposed equipment acquisition.

Where possible, existing governance structures in the health service, such as an equipment/infrastructure management committee, would be used to manage the implementation of the proposed equipment purchase. However, for high-cost and complex equipment purchases, it may be appropriate to establish a specific project team.

The business case will include details of the intended governance structure for the proposed medical equipment acquisition, regardless of whether an existing governance structure will be used.

The business case outlines the terms of reference and composition of the following:

- project sponsor, such as chief executive or executive director
- steering committee
- project team
- working groups.

Project risk management

Risk management is an important part of the implementation plan for the preferred option. The plan will have identified the key risks associated with the preferred option and described the strategy that would be implemented to mitigate the impact of these risks.

The implementation plan identifies who would be responsible for implementing the risk management mitigation strategies and monitoring their impact.

The costs of specific risk-management strategies, where quantifiable, would be identified and incorporated into the financial analysis of the preferred option.

All risks and mitigation strategies are to be recorded in a risk register and regularly reviewed. A suggested format is as follows.

Risk description	Likelihood of occurrence	Consequence	Mitigation strategy
Example: Delay in equipment arriving from overseas	Low	Medium	Extend temporary service arrangements on alternative campus

Note: example table only

Transition planning

The acquisition of an additional or replacement items/system of equipment may require a period of temporary changes to service delivery to enable the equipment to be installed, tested and commissioned.

Health services should develop a transition plan that enables the continuation of service delivery while the additional or replacement equipment is brought into service. This transition plan also provides a basis for identifying risk-management strategies to maintain clinical safety but also contingency measures if there are delays in implementing the equipment.

The transition plan would describe:

- the transition actions relating to the medical equipment acquisition, how they will be achieved and by when
- the responsibility and accountability for the transition actions
- how the transition will be monitored

- what other interdependent actions need to occur to achieve successful transition
- input from stakeholders in the transition process, including identifying and communicating transition actions.

Procurement

The business case outlines the procurement method (such as quotations, tender, preferred supplier panel contract) to be used and the reasons why this is the most appropriate method for acquiring the equipment.

It will also outline any value-for-money procurement and collective purchase arrangements that have been considered.

Project implementation and timing

Timelines and key milestones for implementing the proposed equipment acquisition are outlined in the business case, including key dates and milestones for:

- funding approvals
- any collective purchase decision
- procurement steps, including equipment specifications, quotes/tendering and evaluation
- ordering lead times
- transition
- training
- installation
- commissioning.

The following table provides an example of information to be included in the implementation plan.

Work step	Target completion date	Resource
Example: Develop detailed equipment specifications	30 June 2012	Technical working group
Example: Release tender	3 August 2012	Procurement manager

Note: example table only

Funding strategy

The financial analysis undertaken as part of the options analysis will have identified the estimated total cost of the preferred option, and the estimated increase/decrease in costs associated with the preferred option in comparison with the base case ('do nothing') option.

The business case is to include a funding strategy that identifies the total funding requirement, both capital and recurrent, and all proposed sources of funding over the expected life of the equipment. It is important to note that the funding sources identified must be matched to the type of expenditure to be incurred – that is, capital funding sources may only be applied to capital expenditure.

The funding strategy identifies the steps and approvals required to secure the necessary funding to proceed with the equipment acquisition.

Approvals and sign-off

The business case would be endorsed by the relevant key stakeholders, and have the appropriate level of sign-off by the department/service area head, project sponsor and executive management.

II – Instructions for completing a full lifecyle costing template

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Instructions on how to use the full lifecycle costing template are provided below. It is intended to be a guide to the type of information that would be presented about the whole-of-lifecycle costs associated with the equipment. This information is fundamental to comprehensively assessing the need to replace or add equipment.

The template is provided to the heath service chief executive office on request or as part of information provided to make department submissions.

Using the full lifecycle costing template

Instructions on using the full lifecycle cosing template

The evaluation of asset alternatives involves a number of factors including identifying the most appropriate technology, alignment to service needs and cost. From the cost perspective, comparisons of asset alternatives, whether at the feasibility or evaluation stage, are often based mainly on initial capital costs.

In order to better assess alternative asset choices and value-for-money outcomes, ongoing operating and maintenance costs must be considered, as they form a significant component of the total cost of ownership over the useful life of an asset.

Full lifecycle costing is a process to determine the sum of all the costs associated with an asset or part thereof, including acquisition, installation, operation, maintenance, refurbishment and disposal. It is therefore a key consideration of the asset management framework.

The three key elements of lifecycle costing are the:

- costs of owning and operating an asset
- period of time over which the costs are incurred
- discount rate that is applied to future costs to equate them with present-day costs.

Decision making based on lifecycle costing analysis often involves a combination of both quantitative and qualitative assessments. The quantitative results provide a baseline, but many other factors relevant to a decision may not be quantifiable in terms of costs. These qualitative assessments support the results of the quantitative analysis and will be addressed in the development of a business case template.

General guidance notes

The purpose of a full lifecycle cost analysis is to enable better assessment of alternative asset choices and value-for-money outcomes through considering all the costs associated with an asset over its useful life, including acquisition, installation, operation, maintenance, refurbishment and disposal.

It is intended that the results of the full lifecycle cost analysis undertaken using this template would form part of the quantitative analysis component of a business case supporting the acquisition of an additional or replacement medical equipment item or system.

The full lifecycle costing template assists health services in undertaking a full lifecycle cost analysis for additional or replacement medical equipment items or systems.

It should be noted that this template can be applied to any analysis, regardless of the value of the items or systems being considered. The analysis should cover a range of options, including maintaining the status quo (base case), and comprise the full lifecycle of the equipment being requested.

This template includes a number of cost items. All cost items that have relevance and are material to the item of equipment to be purchased must be included.

> Whether items are material may be assessed based on the extent to which the cost item contributes to the total lifecycle costs (expensive components such as comsumables), or as a percentage of the initial acquisition cost of the item or system.

Where possible, the analysis will identify the total costs rather than incremental costs to ensure the total costs of the equipment are being captured in the analysis.

The comparative analysis on the summary sheet is based on discounted cash flows and is linked back to the individual options being considered. The template automatically calculates these values based on the discount rate entered on the assumptions sheet.

The discount rate to be used to calculate the present value for each option is based on the 10-year Treasury Corporation of Victoria (TCV) bond rate. This rate is published on the TCV website (www.tcv.vic.gov.au). The 10-year bond rate can be found under ‘interest rates’ in the ‘market activity’ section of the TCV website.

All amounts will be expressed exclusive of GST.

Cost factors

Escalation factors

Generally CPI should be used, unless advised by the finance department. Details of different types of cost or revenue escalation are given below, and should be used when relevant to individual types of equipment. This template is a tool to be applied to all types of equipment.

Cost escalation	The estimated annual percentage increase for non-salary-related costs included in the lifecycle cost analysis. The current CPI or inflation estimate is an appropriate measure to use for this escalation factor.
Revenue escalation	The estimated annual percentage increase of the revenue generated by the item of equipment over the period of the lifecycle cost analysis.
Salary escalation	The estimated annual percentage increase for salary-related costs included in the lifecycle cost analysis. EBAs often provide provisions for annual increases in salary and wages. The relevant EBA increase is an appropriate measure for this escalation factor.
None	Use this escalation factor for any revenue or cost items that are expected to either remain fixed or have an uneven profile over the period of the lifecycle. An example of an item that would be fixed over the period of the lifecycle cost analysis is lease payments. An example of an item that may have an uneven profile over the lifecycle costing period could include revenues that gradually increase over a number of years (due to volume growth) then remain fixed for the balance of the life of the equipment.

CPI = consumer price index; EBA = enterprise bargaining agreement

Revenues

External revenue	Revenues that are to be generated from external sources resulting from acquiring the equipment such as private patient fees. Do not include any funding-related revenues such as increased WIES or capital grants received from the department.
Other revenue (specify)	Other significant revenues such as services performed on a fee-for-service basis for other health services associated with the equipment.

WEIS = weighted inlier equivalent separations

Residual values (of equipment to be acquired)

Residual value refers to the estimated value of the proposed equipment to be acquired at the end of its life. This would include any trade-in value on a subsequent replacement item of equipment. Where possible, residual values of similar items provide a suitable guide to give an estimate of any end-of-life residual value.

Initial acquisition costs

Purchase cost	Purchase price of the equipment. If the equipment is procured via a lease arrangement, the annual lease payments should be identified in the leasing costs section of the template.
Delivery and installation costs	Costs associated with having the equipment delivered and installed onsite. This includes freight, foreign exchange costs and transit insurance.
Integration costs	Costs associated with integrating and interfacing the equipment with existing systems and other equipment such as software updates and connections to IT systems.
Facility modifications	Costs associated with modifying the facilities to accommodate the medical equipment such as floor reinforcement, air-conditioning upgrades, filtering systems and protective linings. These costs may also include any costs to remove the equipment being replaced.
Initial training	Initial training costs such as ‘train the trainer’, course materials, specialist/technical support training and service manuals.
Trade-in	Discounts or allowances provided by the supplier for any equipment traded in. Only include actual discounts received. Do not include the written-down value of the item being replaced.

IT = information technology

Leasing costs (if applicable)

Lease payments	Annual leasing costs for the item of equipment being acquired (if purchased via a lease arrangement).
Residual lease payments	Identify (if applicable) any lump-sum residual payments ('balloon payments') payable at the end of the lease term.

Maintenance costs

Scheduled/ preventative maintenance	Regular activities that need to be undertaken to maintain the equipment in safe working order, such as preventative service kits. This would include additional resources required for in-house maintenance and/or maintenance contracts with external service providers.
Decontamination and waste disposal	Costs associated with cleaning, sterilisation, disinfection, decontamination and the disposal of hazardous waste such as radioactive materials or chemicals. Only costs that are directly related to the item of equipment, such as specific chemicals or decontamination equipment, should be included.
Other maintenance costs (specify)	Other significant maintenance costs associated with this type of equipment.

Repairs

Repairs/ unscheduled maintenance	Costs of maintaining the effective life and safe working order of the equipment. For simplicity, and given that repairs are estimates, an annual 'best' estimate of possible repairs is satisfactory. This estimate would be based, where possible, on past experience for the type/brand of equipment and reliability cited by the manufacturer.
Upgrades and refurbishments	Periodic updates to the equipment to maintain it in accordance with statutory or the manufacturer's requirements.
Spare parts and accessories	Costs of replacement spare parts and accessories over the life of the equipment, such as monitor cables.
Other repair costs (specify)	Other significant repair costs associated with this type of equipment.

Operating costs

Staffing costs	Salary and related on-costs associated with employing additional staff to operate and maintain the equipment. Only costs of employing staff in addition to the existing base staffing should be included.
Accreditation and certification	Costs associated with undertaking certifications and compliance audits, and ensuring that the equipment meets professional standards.
Supplies and consumables	Costs of supplies and consumables directly used in operating the equipment.
Ongoing training	Costs for undertaking 'train the trainer', in-house biomedical engineering/engineering/technical support training, refresher courses and the production/acquisition of training material.
Utilities	Energy costs directly associated with operating the equipment where these costs are material and can be reliably estimated.
Licences	Fees and charges associated with licences required to operate and maintain the equipment, such as software.
Other operating costs (specify)	Other significant operating costs associated with this type of equipment.

End-of-life disposal costs (of equipment to be acquired)

These are costs to decommission, remove from service and safely dispose of the equipment at the end of its useful life, including removal costs, freight and 'make good' repairs to the facility. This would be the best estimate at the time of purchase. Where possible, disposal costs of similar items may provide a suitable guide to provide an estimate of these costs.

Full lifecycle cost analysis – options development

Base case and alternative options

The lifecycle cost analysis will compare a range of options including retaining the existing equipment item or systems to deliver the service. This is sometimes referred to as the 'do nothing' option and provides a base case to use as a comparator against alternative options.

The base case option would include all relevant costs associated with continuing the existing service delivery using the equipment currently in place. These costs may include refurbishments, maintenance and the cost of implementing other risk-mitigation strategies to maintain the existing service delivery.

Review the results of the lifecycle cost analysis (sensitivity analysis)

The lifecycle cost analysis process is built on a range of assumptions about current and future cash flows for various types of costs. Each element of the analysis has varying degrees of accuracy and potentially has a different impact on the overall analysis results. It is therefore important to further explore the impact of changes in the values for key costs and how they impact on the overall results. This exercise is usually referred to as a sensitivity analysis.

The sensitivity analysis will involve repeating the evaluation of the lifecycle cost model for a variety of alternative data values. Alternative values are chosen based on the level of uncertainty of the data item and are often structured around a range of values such as best case, most likely case and worst case. For example, if the annual cost of maintenance was estimated to be $12,000 (most likely case) but could range from $5,000 (best case) to $21,000 (worst case), it would be appropriate to investigate the effects on the overall analysis of using these alternative values.

Full lifecycle cost analysis – assumptions

Estimated effective life of the equipment item or system

10 years

Indexation factor

Cost escalation (CPI) should be noted as 2.5 per cent per year unless otherwise advised.

Discount rate

The 10-year TCV bond rate should be used as the nominal discount rate and as an example would be 6.2 per cent per year.

Refer to General guidance notes.

Escalation factors	Year									
	1	2	3	4	5	6	7	8	9	10
Cost	1.00	1.03	1.05	1.08	1.10	1.13	1.16	1.19	1.22	1.25
Revenue	1.00	1.03	1.05	1.08	1.10	1.13	1.16	1.19	1.22	1.25
Salary	1.00	1.03	1.06	1.09	1.13	1.16	1.19	1.23	1.27	1.30
Discount rate (nominal)	1.00	1.06	1.13	1.20	1.27	1.35	1.43	1.52	1.62	1.72
Present value factor (nominal)	1.00	0.94	0.89	0.83	0.79	0.74	0.70	0.66	0.62	0.58

Note: example table only

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Full lifecycle cost analysis – summary analysis

Lifecycle costs of options	Base case	Option 1	Option 2	Option 3
Revenues Revenues				
Residual cash inflows				
Total revenues/cash inflows				
Acquisition costs (net)				
Leasing costs				
Maintenance costs				
Repair costs				
Operating costs				
Disposal costs				
Total all costs/cash outflows				
Total lifecycle cost (present value)				

Note: example table only

Full lifecycle cost analysis – option detail

Lifecycle cost analysis – base case

Brief description of base case option:

Real revenues ($'s)	Escalation factor	Total all years	Year 1	Year 2	Year 3	Year 4	Year 5
Revenues							
External revenue	Revenue	–					
Other revenue (specify)	Revenue	–					
	Revenue	–					
	Revenue	–					
Total revenues		–	–	–	–	–	–
Residual values							
Salvage/disposal value of the equipment	None	–					
Total residual cash inflows		–	–	–	–	–	–
Total all revenues/cash inflows		–	–	–	–	–	–

Real costs ($'s)	Escalation factor	Total all years	Year 1	Year 2	Year 3	Year 4	Year 5
Initial acquistion costs (non-recurring)							
Purchase price	None	–					
Delivery and installation costs	None	–					
Integration costs	None	–					
Facility modifications	None	–					
Training	None	–					
Total acquisition costs		–	–	–	–	–	–
less Trade-in of item being replaced	None	–					
Net acquisition costs		–	–	–	–	–	–
Leasing costs							
Lease payments	None	–					
Residual lease payments	None	–					
Total leasing costs		–	–	–	–	–	–
Ongoing operating and maintenance (recurring)							
Maintenance costs							
Scheduled/preventative maintenance	Cost	–					
Decontamination and waste disposal	Cost	–					
Other maintenance costs (specify)	Cost	–					
	Cost	–					
	Cost	–					
Total maintenance costs		–	–	–	–	–	–
Repairs							
Repairs/unscheduled maintenance	Cost	–					
Upgrades and refurbishments	Cost	–					
Spare parts and accessories	Cost	–					
Other repair costs (specify)	Cost	–					
	Cost	–					
	Cost	–					
Total repair costs		–	–	–	–	–	–
Operating costs							
Staffing costs	Salary	–					
Accreditation and certification	Cost	–					
Supplies and consumables	Cost	–					
Training	Cost	–					
Insurance	Cost	–					
Utilities	Cost	–					
Licences	Cost	–					
Other operating costs (specify)	Cost	–					
	Cost	–					

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Please note that even though the base case option template is shown opposite, the same template is used for each of the options considered as part of the full lifecycle costing analysis.

The template assists health services in preparing a business case to acquire or replace medical equipment. It is intended to be a guide to the extent and type of information that would be presented in developing a business case. Health services may find it necessary to augment the template with additional essential information and evidence to support the business case.

The template is provided to the health service chief executive office on request.

III – Instructions for completing a business case template

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Medical equipment business case

Executive summary

The business case enables decision-makers to plan and identify medical equipment needs and consider the full range of options that include non-asset and asset solutions. The business case template provides guidance on key components that should be included.

Executive summary checklist

Ensure the following has been included:

- ☐ how the equipment or system will meet the identified service need
- ☐ how the acquisition will align to the service objectives of the health service, as well as the department and whole-of-government strategic directions
- ☐ which options are considered for meeting the service need
- ☐ what the short-listed options are, and the basis for their short-listing
- ☐ what the rationale for the preferred option is, based on fitness for purpose, costs, benefits and risks
- ☐ what the readiness to implement and timeframes for implementation are
- ☐ what the lifecycle costs associated with the preferred option are
- ☐ what the budgetary implications for the acquisition are – both recurrent and non-recurrent – and how they will be funded
- ☐ how to plan for implementation, including project management and governance, procurement strategy, post-implementation assessment and project risk management.

Description of medical equipment needs

Introduction and background

Strategic context

Policy statement/strategic objective	Degree of alignment (high/medium/low)	Evidence supporting degree of alignment

Note: example table only

Strategic context checklist

- ☐ Clearly demonstrates alignment with strategic directions for service delivery.
- ☐ References to supporting documents are identified or included as attachments to the business case.

Service profile

Current service profile

Current service profile checklist

Ensure the following has been included, where relevant:

- ☐ types of services/procedures provided
- ☐ number of services/procedures provided
- ☐ service capacity
- ☐ waiting times for procedures
- ☐ patient profile and mix (public, private)
- ☐ service demand, service usage, burden of disease
- ☐ fitness for purpose, use and effectiveness of equipment (capacity to sustain service delivery)
- ☐ relationships with other service providers and models of care.

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Future service profile

Future service profile checklist

Ensure the following has been included, where relevant:

- projected impact of policies and strategies on the delivery of health services and models of care
- projected service demand and usage trends
- estimated service/procedure capacity requirements
- types of services/procedures to be provided
- projected activity levels by service type/procedure
- workforce requirements.

Identified service need

Service profile indicators	Current	KPI/ evidence to support current profile	Future	KPI/ evidence to support future profile

KPI = key performance indicator

Note: example table only

Identified service need checklist

- ☐ The gaps between the current service profile and the future service profile have been clearly outlined.
- ☐ How these identified gaps can be overcome through the proposed equipment acquisition has been outlined.

Options evaluation

Summary of options

Options development

Process for options development

Options development checklist

- ☐ A range of options to meet the identified service need have been developed.
- ☐ The process and criteria for short-listing options have been documented.
- ☐ A 'do nothing' option has been included in the short list.

Options analysis

Qualitative analysis

Evaluation criteria	Base case ('do nothing' option)	Option 1	Option 2	Option 3
Total score				
Average score				

Note: example table only

Qualitative analysis checklist

- ☐ Evaluation criteria have been developed and documented.
- ☐ Appropriate weightings have been applied to each criterion.
- ☐ Each option has been evaluated and scored against the evaluation criteria.

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Financial analysis

Lifecycle costs	Base case ('do nothing' option)	Option 1	Option 2	Option 3
Revenues				
Residual value				
Total revenue				
Acquisition costs				
Leasing costs				
Maintenance costs				
Repair costs				
Operating costs				
Disposal costs				
Total costs				
Total net lifecycle costs (net present cost)				
Score				

Note: example table only

Financial analysis checklist

- ☐ Full lifecycle costing template has been completed and included as an attachment to the business case.
- ☐ Summary data has been presented in tabular form.
- ☐ Each option has been scored.

Overall analysis

	Base case ('do nothing' option)	Option 1	Option 2	Option 3
Qualitative analysis				
Weighted qualitative analysis score (X%)				
Financial analysis				
Weighted financial analysis score (Y%)				
Combined weighted score				

Note: example table only

Overall analysis checklist

- ☐ Weightings have been determined for quantitative analysis and financial analysis.
- ☐ Scores have been calculated based on weightings.
- ☐ Summary analysis has been included.
- ☐ Options have been ranked.

Preferred option

Preferred option checklist

- ☐ The preferred option has been documented in detail.
- ☐ Reasons for being considered the preferred option have been documented.

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Implementing the preferred option

Project management and implementation

Project management and governance

Project management and governance checklist

- ☐ Organisational arrangements have been (or will be) implemented to manage and support the project.
- ☐ Any internal and external resources required to support the project have been identified.
- ☐ Reporting and monitoring processes have been put in place.

Project risk management

Risk description	Likelihood of occurrence	Consequence	Mitigation strategy

Note: example table only

Risk management checklist

- ☐ Key risks have been identified, and rated and recorded in a risk register.
- ☐ Mitigation strategies have been developed and costed (where possible).

Transition planning

Transition planning checklist

- ☐ Transition issues have been identified and documented.
- ☐ Strategies to manage the transition issues have been outlined.

Procurement

Procurement checklist

- ☐ Procurement method has been determined.
- ☐ Rationale for the proposed procurement method has been documented.

Project implementation and timing

Work step	Deadline	Resource

Note: example table only

Project implementation checklist

- ☐ Key work steps have been identified.
- ☐ Resources required have been identified and secured.
- ☐ Realistic timeframes and milestones have been determined.

Funding strategy

Funding strategy checklist

- ☐ Funding requirements have been fully costed.
- ☐ Proposed funding strategy and sources have been documented.
- ☐ Steps and approvals required to obtain funding have been documented.

Approvals and sign-off

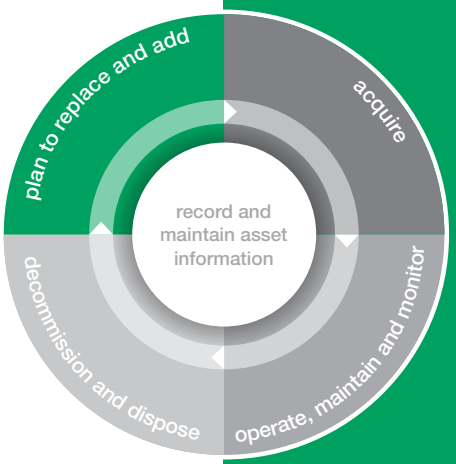
Approvals checklist

- ☐ Documentation has been provided to the relevant parties/delegated officers.
- ☐ Endorsements from key stakeholders and signatures have been obtained from relevant authorised/delegated parties.

C2.4 Checklist for use when a business case is not required

Purpose	Acquisitions below the business case threshold do not require the preparation of a full business case, but the proposals still benefit from a systematic approach to their justification and assessment. The checklist here provides that guidance.
Summary	The checklist provides a series of tests to evaluate proposed acquisition.
Framework references	B2.5.2 — Prepare a checklist
Associated tools	C2.2 — Requirement for a business case
Version 1.0, 2011	

C Checklist



Checklist for use when a business case is not required

The following checklist is to assist health services to evaluate proposed acquisitions.

Sections	Key points	Tick where relevant	Comments where applicable
1. Equipment	Item and description of equipment	☐	
	Cost of equipment and what the costs are based on:		
	• ball-park estimate	☐	
	• broad estimate	☐	
	• rule of thumb	☐	
	• estimate – preliminary	☐	
	• estimate – detailed	☐	
	• indicative quote	☐	
	• firm quote	☐	
	Where will the equipment be located?	☐	
	What are the major functions of the item and how do they relate to the services it supports?	☐	
	Reason for request for equipment (replacement or additional?). Relate to asset management plan	☐	
	Is anywhere else within the health service already using similar equipment? If so, outline where and any differences in use	☐	
	What qualifications are required to use the equipment (consider direct usage and interpretation of any related data)?	☐	
	If training is required, is it feasible within the budget and skill set of proposers that appropriate training could/will be obtained?	☐	
2. Clinical need	What evidence is presented that the technology is needed for this patient or group?	☐	

Sections	Key points	Tick where relevant	Comments where applicable
3. Clinical benefit and safety	State the benefits of purchasing the equipment (clinical and financial)	☐	
	Is the equipment TGA approved?	☐	
	Does the equipment meet Australian standards?	☐	
4. Current service profile	Types of services/procedures provided	☐	
	Number of services/procedures provided	☐	
	How will the equipment meet the identified service need?	☐	
	Service capacity for procedures	☐	
	Waiting times, patient profile and mix (public, private)	☐	
	Service demand, utilisation, burden of disease	☐	
	Fitness for purpose, use and effectiveness of equipment (capacity to sustain service delivery)	☐	
	Relationships with other service providers and models of care	☐	
5. Future service profile checklist	Projected impact of policies and strategies on the delivery of health services and models of care	☐	
	Projected service demand and usage trends	☐	
	Estimated service/procedure capacity requirements	☐	

Sections	Key points	Tick where relevant	Comments where applicable
	Types of services/procedures to be provided	☐	
	Projected activity levels by service type/procedure	☐	
	Workforce requirements	☐	
6. Lifecycle costs associated with equipment For example, budgetary implications – recurrent and non-recurrent – for the acquisition	Estimated effective life of equipment	☐	
	Identification of all revenues associated with equipment	☐	
	Acquisition costs	☐	
	Capital/lease costs	☐	
	Fees and licences	☐	
	Freight and duties	☐	
	Installation costs (IT, building works, utilities)	☐	
	Operating costs (existing and new equipment)	☐	
	Maintenance and repairs	☐	
	Upgrades	☐	
	Consumables	☐	
	Energy	☐	
	Cleaning	☐	
	Disposal	☐	
	Disposal costs	☐	
	Residual value	☐	

Sections	Key points	Tick where relevant	Comments where applicable
7. Options considered for equipment-related provision of service For example, rationale for alternate delivery methods and leasing	Alternative delivery methods	☐	
	Leasing	☐	
	Consumable contract	☐	
8. Preferred option For example, rationale for preferred option based on fitness for purpose, costs, benefits and risks		☐	
9. Implementation For example, timeframes, governance, procurement strategy	Project management	☐	
	Governance	☐	
	Risk management	☐	
	Procurement strategy Adherence to government and health service policies related to procurement associated with cost of equipment	☐	
	Post-implementation assessment	☐	
10. Expected funding sources	Identified funding source	☐	
	Applications for external funding completed	☐	
11. Replacement planning	Proposed funding source for replacing the item in the future	☐	

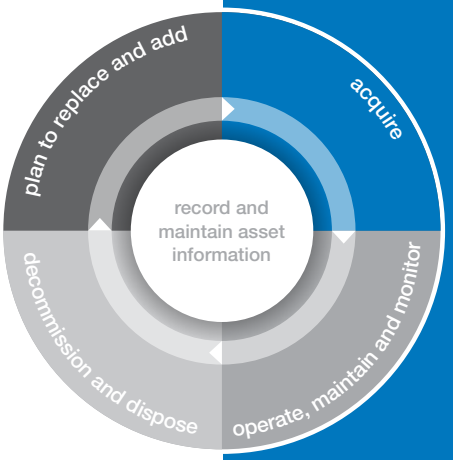
IT = information technology; TGA = Therapeutic Goods Administration

C3.1 Preparing equipment specifications

Purpose	To ensure the procurement process for medical equipment is based on comprehensive and accurate specifications of the requirement.
Summary	This information sheet outlines the functional, technical and environmental considerations that need to be included in equipment specifications.
Framework references	B3.2 — Prepare equipment specifications for the preferred option

Version 1.0, 2011

I Information sheet



Preparing equipment specifications

General specification framework

Background

Specifications, where possible, should be written in terms of outputs or function required. A specification must be clear and complete, and accurately define what is expected from a supplier.

Equipment specifications would be based on the final endorsed business case or checklist that supports the purchase of this equipment. The business case document/checklist sets out many of the attributes and specifications required for the asset to support the key service delivery elements.

The initial specifications include:

- a brief description of the health service, location and campus
- a brief explanation of how the equipment will fit into the health service plan for delivery of services, for example, sole item, integration with other items, or single versus multiple campus deployment.

Functional specification

The following provides examples of some of the technical information that may be required.

Location and department/area	Location and department/area where this equipment will be used, including brief description if relevant
Description of user	Description of who will use the equipment (such as medical, nursing, allied health or home care staff)
Description of functionality	The specific clinical functions required from the equipment, for example: • patient monitor – electrocardiogram (ECG), blood pressure, temperature • patient hoist to assist a nurse to get a patient out of bed, and move them to a chair or ensuite • angiography system, cardiac – to perform full range of diagnostic and interventional procedures, including angiography, angioplasty, coronary artery stenting and electrophysiology (EP) studies

Description of connections/ interaction with other medical equipment/systems	Requirements for connection to any other equipment or system, including interface details, for example: • Picture Archival Communication System (PACS); vendor XXXX, version YYYY • Hospital Information System (HIS); vendor ZZZZ, version TTTT • Radiology Information System (RIS); vendor UUUU, version VVVV • network printer or recorder (make AAAA, model BBBB) • network operating system and hardware

Technical specifications

Examples of possible technical specifications are listed below.

1. Patient characteristics	Critical (patient) population limits for clinical utility, for example: • weight range of patients for beds, operating theatre tables, trolleys • age/weight range of patients for ventilators • target clinical group, such as patient trolleys for use with bariatric paediatric patients, or ventilators
2. Equipment physical requirements	Size of screen Number of traces onscreen Wheel size Handles Side rails Clipboard holder Bed length, width, height
3. Options and accessories required	Cable management hardware Mounting brackets Interface cables Sensors, electrodes, batteries, paper Roll stand/trolley Operating software back-up

4. Modes of operation required	For example: • ventilators – volume/pressure modes required, invasive/non-invasive, fixed/mobile • electrosurgery – number and type of waveforms, foot/hand activation • X-ray – types of exam performed, patient size/weight, digital/analogue, mobile/fixed
5. Output values/ranges	Minimum acceptable output ranges where applicable, for example: • defibrillators – energy (joules) • electrosurgery – output power (watts) • operating light – light power (lumen) • pumps – infusion rates (millilitres per hour) • X-ray – HV* and current (kV, mA) • beds/trolleys – height adjustment range
6. Critical performance characteristics	Battery life and capability for rechargeable batteries Memory capacity Accuracy (volume/time delivered, delivered dose) Resolution (pixels, dots per inch) Capacity (volume of steriliser) Speed (whole body scan time, sterilisation cycle time)
7. Alarms	Type (pressure, temperature, rate) Audible Visible Remote Conditions for resetting

HV = high voltage

8. Usage requirements	Quantitative measures of how heavily the equipment will be used, for example: • operating theatre lights – hours of operation per day • chest X-ray – exposures per day • haemodialysis – shifts per day • steriliser – cycles per day
9. Environmental conditions	Utilities, such as: • standby and operational energy use • ease of shutdown and reboot (to avoid standby when not in use) • heat gain (in standby and operational modes) • water use • water capture and reuse capability • heating and cooling requirements • drainage requirements Space availability, floor plan Floor loading limitations (if any) Hazardous outputs/waste Finishes required on surfaces to meet infection control or cleaning requirements Temperature ranges for storage and operation of item
10. Regulatory and standards compliance	Australian Register of Therapeutic Goods Environment Protection (Industrial Waste) Resource Regulations 2009 Standards Australia,[1] International Electrotechnical Commission (IEC) or International Organization for Standardization (ISO) Type testing, CE (conformance) marking, declaration of conformity Relevant professional college standards

1 **AS/NZS 3551:2004** – *Technical management programs for medical devices*, Section 3.2.2

11. Occupational health and safety	Conformance to safety standards Compliance with the Victorian Nursing Back Injury Prevention Project Weight of asset
12. Sustainability	Manufacturer policy on sustainability End-of-life disposal Hazardous materials Recycled content of product (excluding packaging) Packaging materials (waste avoidance, minimisation and removal of packaging) Product stewardship/end-of-life disposal (including recyclability of product components)
13. Warranty and guarantee	Duration and terms of warranty Excluded items Items with pro-rata warranty
14. Training of users	Requirements for operator staff Direct to users or train-the-trainer model Training night/weekend shift staff
15. Waste management	Examples of wastes Reuse options

16. Maintenance	Availability of service personnel Terms and price(s) of maintenance contract Option of remote access for off-site monitoring and maintenance Availability and cost of maintenance training Availability and cost of service tools and software Spare parts supply and cost Critical spare parts availability (time to deliver) Provision of loan equipment during failure Service manual, hard copy/soft copy User manual, hard copy/soft copy Record changes to external casing or internal software

Specifications must comply with the Department of Treasury and Finance's *Good practice advice on specification writing*.[2]

Refer to Health Purchasing Victoria's website for more procurement information and associated contacts.[3]

2 www.vgpb.vic.gov.au/CA2575BA0001417C/WebObj/D0956929GUIDELINEWEBCOPYSpecificationWriting/$File/D09%2056929%20GUIDELINE%20WEB%20COPY%20Specification%20Writing.DOC

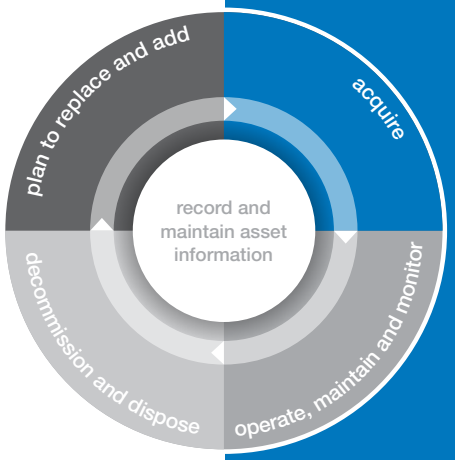
3 www.hvp.org.au

C3.2 Procurement

Purpose	To ensure government requirements for probity and value for money are realised when acquiring medical equipment.
Summary	This information sheet describes the documentation required for procuring medical equipment and refers to the guidelines of the Victorian Government Purchasing Board (VGPB).
Framework references	B3.4 — Acquire equipment

Version 1.0, 2011

Information sheet



Procurement requirements

The purchase of all medical equipment assets must comply with Department of Treasury and Finance requirements. Health services are responsible to ensure the following probity directives are met:

- standards of probity required under Victorian Government Purchasing Board (VGPB) guidelines
- the Victorian Government's disclosure policy *Ensuring openness and probity in Victorian Government contracts*[1] – public health services are required to meet the government disclosure policy and inform appropriate staff of hospital procurement and disclosure policies
- recommendations contained in the ombudsman's report *Probity controls in public hospitals for the procurement of non-clinical goods and services* – health services are required to review their probity controls and take the recommendations into consideration.

Local purchasing policies developed by health services must be documented and meet the minimum standards set by the VGPB.

Major purchases require the following documentation:

- equipment specifications
- selection criteria and weighting
- a copy of purchase contract covering procurement
- a response document that identifies each item requiring a response from the vendor (for example, an itemised cost table, detailed specification compliance table, copies of Australian Register of Therapeutic Goods entries, insurance and financial details).

1 www.health.vic.gov.au/procurement/index.htm

The information required before a purchase can be made includes:

- the cost of the base unit
- the cost of options, consumables and accessories
- maintenance requirements
- a critical spare parts list
- spare parts and service personnel location, and indicative response/delivery times
- user training requirements, and what is provided by the vendor
- maintenance training provided to health service staff – maintenance training options available
- special tools/software required for maintenance
- maintenance contracts available – together with cost and price indexing criteria
- the vendor's policy on software updates and upgrades – costs, availability, expected support life
- the vendor's policy on replacement parts – costs, availability, expected support life
- a warranty – duration, options to extend, exclusions
- installation and integration costs – including infrastructure upgrades required
- value for money and collective purchase arrangements.

For further information about the key requirements, check the VGPB[2] guidelines and the Health Purchasing Victoria website.[3]

2 www.vgpb.vic.gov.au/domino/web_notes/vgpb/procport.nsf?Open

3 www.hvp.org.au

C4.1 Maintenance

Purpose	To provide information about different aspects of maintenance.
Summary	This information sheet covers: • **maintenance tasks** — lists key maintenance tasks • **maintenance records** — lists the rationale for record keeping and the information required for effective record keeping • **maintenance guidelines** — lists other important guidelines for maintenance activities.
Framework references	B4.2 — Maximise the effective life of the asset
Version 1.0, 2011	

I Information sheet

Maintenance

Maintenance tasks

Maintenance tasks may include:

- operational verification (performance testing)
- calibration
- routine repair or replacement of aged or worn components (scheduled, preventive or planned maintenance)
- planned refurbishment or upgrades during the life of the asset
- verification of safety of equipment (safety testing)
- breakdown repair (unscheduled maintenance)
- procurement and maintenance of spare parts, if required, to minimise downtime.

Maintenance records

Records of asset details and services performed on those assets are required to:

- aid planning and implementation of maintenance plans
- demonstrate maintenance has been performed
- identify the onset of emerging problems
- aid the planning of replacement assets
- facilitate any relevant equipment recalls or hazard alerts.

Maintenance records need to include the following information:

- an inventory record for each item of medical equipment
- a planned maintenance schedule
- the history of every maintenance intervention for each item on inventory
- safety recalls and incidents
- service contract details
- service manual details.

Maintenance guidelines – information sources

Sources of information on maintenance guidelines include:

- original equipment manufacturer operator, service and maintenance manuals
- **AS/NZS 3551** – *Technical management programs for medical devices*
- **AS/NZS 3760** – *In-service safety inspection and testing of electrical equipment*[1]
- **AS/NZS 4360:2004** – *Risk management*[2]
- **AS/NZS ISO 31000** – *Risk management – principles and guidelines*[3]
- College of Biomedical Engineers 2008, *Clinical engineering standards of practice*, Engineers Australia
- Nordic Co-operative group for medical technology 2002, *Nordic guidelines for good clinical engineering practice*
- DB 2006(05), *Managing medical devices*, Medicines and Healthcare products Regulatory Agency (MHRA)
- **ANSI/AAMI EQ56:1999** – *Recommended practice for a medical equipment management program*.

1 www.engineersaustralia.org.au/colleges/biomedical/advocacy/advocacy_home.cfm

2 http://hct3.sam.lt/pdf/A1-8-MedEquipGuide.pdf

3 www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON2025142

C4.2 Setting up maintenance contracts

Purpose	To provide information about maintenance guidelines, and setting up tasks and records.
Summary	This information sheet provides guidance on maintenance planning, including the definition of maintenance tasks and the importance of maintenance records.
Framework references	B4.2.2 — Set up maintenance contracts

Version 1.0, 2011

I **Information sheet**

Setting up maintenance contracts

Any contractual agreement with a maintenance and/or repair service provider would specify the level and type of service required by the responsible organisation and include, where appropriate:

- reference to the manufacturer's written instructions
- the availability, source and traceability of spare parts
- notification of any changes, including the use of alternative spare parts or methods
- meeting with the contractor
- training of staff
- quality assurance systems
- the requirement for adequate record keeping
- use of subcontractors
- response times
- loan equipment
- disposal of obsolete equipment, parts and waste.

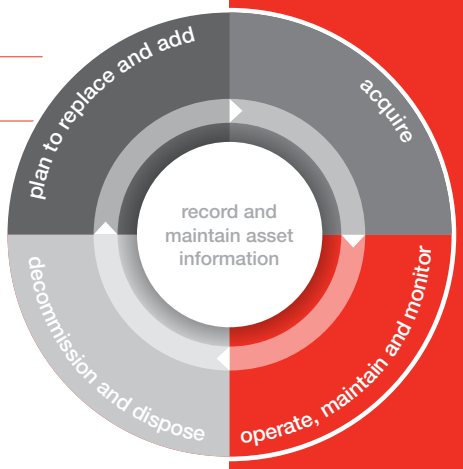
Legal advice would be sought in drawing up contracts, including specialist advice when specific legislation covers the equipment, such as the *Radiation Safety Act 1999* or *Occupational Health and Safety Act 2004*.[1]

1 Nordic Co-operative group for medical technology 2002 *Nordic guidelines for good clinical engineering practice*, Section 12 (http://hct3.sam.lt/pdf/A1-8-MedEquipGuide.pdf); DB 2006(05) *Managing medical devices,* Section 8.3 (www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON2025142)

C4.3 Assessing and rating risks

Purpose	This document indicates when a risk assessment of an item of medical equipment would be undertaken, outlines the methodology and the procedure, and suggests how the findings would be dealt with.
Summary	This document describes a risk assessment procedure and identifies a number of commonly occurring risks (clinical, Occupational Health and Safety (OHS) and service availability) that are applicable to medical equipment. It explains how the level of risk can be established and illustrates the actions that might be taken to manage them.
Framework references	B4.3.2 — Assess risks
Version 1.0, 2011	

Information sheet



Assessing and rating risks

The risk assessment and rating of individual items of medical equipment would be part of the risk management program of each health service and would 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.

The guiding principles for any robust risk assessment tool are:

- consistency – with previous ratings, across agencies and between health service departments/areas
- clarity – able to be used without confusion
- credibility – accepted by stakeholders, the Department of Treasury and Finance, health service CEOs and the department
- verifiable – evidence based
- identifiable – assessment result (risk rating) can be drilled down to determine the particular risk being assessed
- appropriate – aligned with national and international risk management standards such as AS 4360 and ISO 31000,[1] and professional guidelines.

When to do a risk assessment

A risk assessment is required in the following situations:

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

On acceptance

Critical risks need to be identified on acceptance and controls put into place before the equipment is used. These controls include a maintenance plan for components subject to wear and equipment operating rules to reduce OHS issues.

1 Australian and international risk management standards – **AS 4360** and **ISO 31000**: *Risk management*.

Periodically through the life of an asset

Periodic review of risk ratings is required to recognise changes that occur through the life of an asset. Periodic assessment is not intended to individually rate each asset in the inventory but to review any changed circumstances. These might include an annual review of items rated high-risk level 1 or level 2, or the receipt of an end-of-support-life letter for a particular device type.

When the fitness for purpose of the equipment is assessed to be below acceptable standards

When one of the regularly conducted fitness-for-purpose assessments reveals that a particular item of equipment fails to meet the minimum acceptable standard, the level of risk needs to be assessed and the appropriate action determined.

Where a critical incident involves an asset

Critical incidents involving equipment must be investigated. Where the equipment is identified as contributing to the incident, a review of the asset risk assessment is required to determine if a new risk has been identified, what controls can be put in place to mitigate that risk, what outstanding risk remains and how that risk would be managed.

Risk is a function of the likelihood and consequence of an adverse event. The *Medical equipment asset management framework* (MEAMF) risk rating system uses a four-point scale from level 1 (highest risk) to level 4 (lowest risk). By considering the likelihood and consequence for each identified adverse event under consideration, risk can be rated using Tables 1–2 overleaf. When a number of risks have been assessed, the overall risk rating for the equipment is the highest rated of the risks considered. The ratings that are determined for likelihood and consequence (for a particular equipment-related adverse event) relate to the fitness for purpose of the equipment at the time the assessment is made.

MEAMF risk rating system

Risk is a function of the likelihood and consequence of an adverse event. The MEAMF risk rating system uses a four-point scale from level 1(highest risk) to level 4 (lowest risk).

The ratings that are determined for likelihood and consequence (for a particular equipment-related adverse event) relate to the fitness for purpose of the equipment at the time the assessment is made.

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

- clinical risk (patient safety)
- OHS risk
- service availability risk.

The likelihood and consequences of risks in each category are assessed.

Table 1: Critical risk levels

		Likelihood				
		Rare	**Unlikely**	**Possible**	**Likely**	**Almost certain**
Consequence	Extreme	**Level 2**	**Level 2**	**Level 1**	**Level 1**	**Level 1**
	Major	**Level 3**	**Level 2**	**Level 2**	**Level 1**	**Level 1**
	Moderate	**Level 4**	**Level 3**	**Level 2**	**Level 2**	**Level 1**
	Minor	**Level 4**	**Level 4**	**Level 3**	**Level 3**	**Level 2**
	Insignificant	**Level 4**	**Level 4**	**Level 4**	**Level 3**	**Level 3**

Note: level 1 is the highest critical risk level and level 4 the lowest

By considering the likelihood and consequence for each identified adverse event the risk can be rated. An individual item of equipment is assessed using the critical risk categories, and the overall risk rating for the equipment is determined by using the highest risk rating from the risks considered. For example, a ventilator has the following risk ratings against the critical risk categories: (clinical risk = L1), (OHS = L3), (service availability = L2). The combined critical risk rating would be level 1 – the highest critical risk.

Likelihood

The criteria and descriptions in Table 2 provide guidance on rating likelihood by providing descriptions based on:

- whether an event has happened
- the conditions under which the event happened (exceptional or normal) and whether it will recur
- how soon it might recur.

Table 2: Likelihood rating

Likelihood rating	Description	Evidence for rating
Rare	No demonstrated history of this event Possible it will occur in exceptional circumstances Less frequent than once every three years	
Unlikely	Has occurred in another health service Has occurred once in three years	Media report of incident Published hazard report, for example, Therapeutic Goods Administration (TGA), ECRI Institute (ECRI)
Possible	Has occurred with this asset or one with the same characteristics in this health service Has occurred at least once a year	Service history of asset(s) showing occurrence of risk Incident report showing occurrence of risk
Likely	Has occurred more than once with this asset or an asset with the same characteristics in this health service Has occurred two to three times in the past year	Service history of asset(s) showing more than one occurrence of risk Incident reports showing more than one occurrence of risk
Almost certain	History of multiple occurrences with this asset or an asset with the same characteristics in this health service History of increasing failures Has occurred more than three times in the past year	Service history of asset(s) showing multiple occurrences of risk Incident reports showing multiple occurrences of risk

Comparison with previous risk rating systems

The risk rating system outlined in this document is different to that used previously by Victorian health services to rate medical equipment. These changes have been made to ensure alignment with Australian and international risk management standards.

One change has been the descriptions used for both consequence and likelihood ratings. These are summarised in Table 3, showing the alignment between the MEAMF and former rating systems.

Table 3: Comparison of the former risk classification system and MEAMF

Rating	Previous risk levels	MEAMF risk levels
Consequence	High	Extreme Major Moderate
	Medium	Minor
	Low	Insignificant
	None	Not rated
Likelihood	Daily	Almost certain
	Monthly	Likely
	6-monthly	Possible
	5-yearly	Unlikely
	20-yearly	Rare

Another change is the risk tables that map the risk ratings to an overall risk level for the item being assessed. The number of risk levels used has dropped from seven to four. The level 5 to 7 risks previously assigned are now represented by risk level 4 in the MEAMF. The correlation between these two systems is shown in Table 4.

Reconciliation of differences with risk rating systems

Table 4: Correlation between previous and MEAMF risk levels

		Likelihood					
		Rare	Unlikely	Possible	Likely	Almost certain	
Consequence	Extreme	L2	L2	L1	L1	L1	Greater level of differentiation for higher risks
	Major	L3	L2	L2	L1	L1	
	Moderate	L4 L5	L3 L4	L2 L3	L2 L2	L1 L1	High
	Minor	L4 L6	L4 L5	L3 L4	L3 L3	L2 L2	Medium
	Insignificant	L4 L6	L4 L6	L4 L3	L3 L6	L3 L6	Low
		L7	L7	L7	L7	L7	Insignifcant
		20-yearly	5-yearly	6-monthly	Monthly	Daily	
		Previous risk levels					

Note: former risk levels are identified in blue

The MEAMF gives greater discrimination in the risk ratings at the higher risk levels as a result of the additional consequence categories at these levels, while maintaining correlation with the previous risk levels.

Consequences

Criteria and descriptions for the 'consequence' rating are described in each of the three critical risk categories below.

1. Clinical risk

Clinical risk (risk to patient) rates the impact of, and the potential for, the equipment not meeting its intended function resulting in:

- misdiagnosis, for example, due to clinically significant deterioration of the image quality in an X-ray machine
- inaccurate delivery, for example, failure of an infusion pump during treatment
- injury, for example, as a consequence of a ventilator failure.

To check if the risk is attributable to the specific item of equipment apply a 'reasonable person' test – that is, ask, 'If I replaced this asset with a new asset, would this risk disappear?' If the answer is 'yes', then that risk is attributable to the asset.

Table 5 provides guidance on the 'consequence' rating as it relates to 'clinical risk'.

Table 5: 'Consequence' rating for 'clinical risk'

Consequence rating	Description	Evidence for rating
Extreme	Asset is a contributory factor in an unexpected patient death or near miss unrelated to the normal course of illness and differing from the immediate expected outcome Asset is a contributory factor in national reportable sentinel events	Sentinel event report Root cause analysis of event or near miss Health service incident report showing occurrence of risk or near miss
Major	Asset is a contributory factor in a permanent disabling injury or near miss affecting function (sensory, motor, physiological, intellectual) unrelated to a patient's illness	Health service incident report showing occurrence of risk or near miss
Moderate	Asset is a contributory factor in a temporary disabling injury or near miss affecting function (sensory, motor, physiological, intellectual) unrelated to a patient's illness Asset is a contributory factor in a permanent lessening of bodily function or near miss (sensory, motor, physiological, intellectual) unrelated to a patient's illness	Health service incident report showing occurrence of risk or near miss
Minor	Asset is a contributory factor in increased treatment or investigations for outpatients but not requiring admission Asset is a contributory factor in requiring increased length of stay for inpatients	Health service incident report showing occurrence of risk
Insignificant	Asset is a contributory factor in a minor injury requiring first aid	Nil

Table 6 over the page uses both likelihood and consequence values to determine a rating for each 'clinical risk'.

Table 6: ‘Clinical risk’ determined by likelihood and consequence values

				Likelihood				
				Rare	Unlikely	Possible	Likely	Almost certain
				☐ No demonstrated history of event ☐ Possible in exceptional circumstances ☐ Has occured less frequently than once every 3 years	☐ Has occurred somewhere ☐ Has occured at least once every 3 years	☐ Has occurred with this asset ☐ Has occurred at least once a year	☐ Has occurred more than once with this asset ☐ Has occurred at least 2–3 times a year	☐ History of increasing failure ☐ Has occurred more than 3 times in a year
			Evidence of risk		☐ Media report of incident ☐ Published hazard report (such as TGA, ECRI)	☐ Service history showing occurrence of risk ☐ Incident report showing occurrence of risk	☐ Service history showing more than 1 occurrence of risk ☐ Incident reports showing more than 1 occurrence of risk	☐ Service history showing multiple occurrences of risk ☐ Incident reports showing multiple occurrences of risk
Consequence	**Extreme**	☐ Unexpected death ☐ Reportable sentinel event	☐ Sentinel event report ☐ Root cause analysis of event or near miss ☐ Health service incident report showing occurrence of risk or near miss	**Level 2**	**Level 2**	**Level 1**	**Level 1**	**Level 1**
	Major	☐ Permanent disabling injury (sensory, motor, physiological, intellectual) unrelated to patient’s illness	☐ Health service incident report showing occurrence of risk or near miss	**Level 3**	**Level 2**	**Level 2**	**Level 1**	**Level 1**
	Moderate	☐ Temporary loss or permanent lessening of bodily function (sensory, motor, physiological, intellectual) unrelated to the natural course of patient’s illness	☐ Health service incident report showing occurrence of risk or near miss	**Level 4**	**Level 3**	**Level 2**	**Level 2**	**Level 1**
	Minor	☐ Increased treatment or investigations but not admission of outpatient ☐ Requires increased length of stay for inpatient	☐ Health service incident report showing occurrence of risk or near miss	**Level 4**	**Level 4**	**Level 3**	**Level 3**	**Level 2**
	Insignificant	☐ Minor injury requiring first aid ☐ Near miss	Nil	**Level 4**	**Level 4**	**Level 4**	**Level 3**	**Level 3**

2. Occupational health and safety risk

OHS risk rates the impact of, and potential for, staff members being injured due to:

- asset failure or breakage during use
- radiation from the equipment, for example, scatter radiation from an X-ray machine
- inhaling dangerous chemicals, for example, gluteraldehyde from an open washing system
- poor ergonomics, for example, from a bed that is not easily adjusted.

OHS risk refers to the risk that remains after applying all the suitable risk minimisation strategies during equipment commissioning and training of users. This equipment-related risk is separate to risks due to lack of orientation or staff training, staff knowledge of equipment operation, or failure to use protective equipment.

Table 7: ‘Consequence’ rating as it relates to the ‘OHS risk’

Consequence rating	Description	Evidence for rating
Extreme	Asset is a contributory factor in an unexpected staff/visitor death or near miss	Sentinel event report Root cause analysis of event Health service incident report showing occurrence of risk or near miss
Major	Asset is a contributory factor in a permanent disabling injury or near miss affecting function (sensory, motor, physiological, intellectual)	Health service incident report showing occurrence of risk or near miss
Moderate	Asset is a contributory factor in a temporary disabling injury or near miss affecting function (sensory, motor, physiological, intellectual) Asset is a contributory factor in a permanent lessening of bodily function or near miss (sensory, motor, physiological, intellectual)	Health service incident report showing occurrence of risk or near miss
Minor	Asset is a contributory factor in treatment or investigations for a staff member but not requiring admission	Health service incident report showing occurrence of risk
Insignificant	Asset is a contributory factor in a minor injury requiring first aid	Nil

Table 8 over the page uses both likelihood and consequence values to determine a rating for each ‘OHS risk’.

Table 8: ‘OHS risk’ determined by likelihood and consequence values

				Likelihood				
				Rare	Unlikely	Possible	Likely	Almost certain
				☐ No demonstrated history of event ☐ Possible in exceptional circumstances ☐ Has occured less frequently than once every 3 years	☐ Has occurred somewhere ☐ Has occured at least once every 3 years	☐ Has occurred with this asset ☐ Has occurred at least once a year	☐ Has occurred more than once with this asset ☐ Has occurred at least 2–3 times a year	☐ Is expected to re-occur in a short period of time ☐ History of increasing failure ☐ Has occurred more than 3 times a year
			Evidence of risk		☐ Media report of incident ☐ Published hazard report (such as TGA, ECRI)	☐ Service history showing occurrence of risk ☐ Incident report showing occurrence of risk	☐ Service history showing more than 1 occurrence of risk ☐ Incident reports showing more than 1 occurrence of risk	☐ Service history showing multiple occurrences of risk ☐ Incident reports showing multiple occurrences of risk
Consequence	**Extreme**	☐ Death of staff or visitor	☐ Sentinel event report ☐ Root cause analysis of event or near miss ☐ Health service incident report showing occurrence of risk or near miss	**Level 2**	**Level 2**	**Level 1**	**Level 1**	**Level 1**
	Major	☐ Permanent disabling injury (sensory, motor, physiological, intellectual)	☐ Health service incident report showing occurrence of risk or near miss	**Level 3**	**Level 2**	**Level 2**	**Level 1**	**Level 1**
	Moderate	☐ Temporary loss or permanent lessening of bodily function (sensory, motor, physiological, intellectual)	☐ Health service incident report showing occurrence of risk or near miss	**Level 4**	**Level 3**	**Level 2**	**Level 2**	**Level 1**
	Minor	☐ Treatment/investigations but not admission to hospital ☐ Lost time due to injury ☐ Restricted duties due to injury	☐ Health service incident report showing occurrence of risk or near miss	**Level 4**	**Level 4**	**Level 3**	**Level 3**	**Level 2**
	Insignificant	☐ Minor injury requiring first aid ☐ Near miss	Nil	**Level 4**	**Level 4**	**Level 4**	**Level 3**	**Level 3**

3. Service availability risk

Service availability risk rates the contribution of, and potential for, an asset failure resulting in an inability to deliver an established clinical program.

Examples of 'service availability risks' include the following.

- This is the only equipment in the health service providing this clinical procedure or diagnosis.
- There is no reserve capacity in the event of equipment failure. Even though multiple assets exist, each asset is fully used.
- There is no local supplier for this equipment; if it fails, there will be a substantial delay before it can be repaired.
- If the equipment breaks down it would cause detrimental impacts across a number of health programs; for example, the failure of the computed tomography scanner may lead to
  - the emergency department going on bypass
  - delays in the outpatient clinic
  - impacts on inpatient scanning services.

When appropriately applied, this risk will assess a clinical service operating at its current capacity. It does not aim to identify or address gaps or potential growth in the service delivery, equipment commissioning risks or service start-up issues.

Table 9 over the page provides guidance on the 'consequence' rating as it relates to 'service availability risk'.

Table 9: ‘Consequence’ rating for ‘service availability risk’

Consequence rating	Description	Evidence for rating
Extreme	Loss of, or indefinite closure of, a particular clinical service	Health service articulation of how this service is dependent on the asset
Major	Major impairment of a clinical service Multiple cancellations of surgery Temporary closure of more than one critical care bed or operating theatre	Health service articulation of how this service is dependent on the asset
Moderate	Moderate impact on a clinical service resulting in increased waiting times for an extended period Moderate impact on a clinical service resulting in decreased throughput for an extended period Temporary closure of one critical care bed or operating theatre	Health service articulation of how this service is dependent on the asset
Minor	Temporary reduced efficiency Temporary reduced throughput	Health service articulation of how this service is dependent on the asset
Insignificant	No loss of service	Nil

Table 10 over the page uses both likelihood and consequence values to determine a rating for each ‘service availability risk’.

Table 10: ‘Service availability risk’ determined by likelihood and consequence values

			Likelihood				
			Rare	**Unlikely**	**Possible**	**Likely**	**Almost certain**
			☐ No known history of event ☐ Possible in exceptional circumstances ☐ Has occured less frequently than once every 3 years	☐ Has occurred somewhere ☐ Has occured at least once every 3 years	☐ Has occurred with this asset ☐ Has occurred at least once a year	☐ Has occurred more than once with this asset ☐ Has occurred at least 2–3 times a year	☐ Is expected to re-occur in a short period of time ☐ History of increasing failure ☐ Has occurred more than 3 times a year
		Evidence of risk		☐ Media report of incident ☐ Published hazard report (such as TGA, ECRI)	☐ Service history showing occurrence of risk ☐ Incident report showing occurrence of risk	☐ Service history showing more than 1 occurrence of risk ☐ Incident reports showing more than 1 occurrence of risk	☐ Service history showing multiple occurrences of risk ☐ Incident reports showing multiple occurrences of risk
Consequence	**Extreme**	☐ Complete loss, or indefinate closure, of a clinical service ☐ Loss of an essential service resulting in shut down of a service, unit or facitily	**Level 2**	**Level 2**	**Level 1**	**Level 1**	**Level 1**
	Major	☐ Major impairment to a clinical service ☐ Multiple cancellations of surgery ☐ Closure of more than 1 operating room or critical care bed ☐ Major damage to 1 or more services or departments affecting the whole facility	**Level 3**	**Level 2**	**Level 2**	**Level 1**	**Level 1**
	Moderate	☐ Moderate increase in waiting times for an extended period ☐ Moderate decrease in throughput for an extended period ☐ Closure of 1 operating room or critical care bed ☐ Disruption to 1 service or department for 4 to 24 hours	**Level 4**	**Level 3**	**Level 2**	**Level 2**	**Level 1**
	Minor	☐ Temporary reduced efficiency ☐ Temporary reduced throughput ☐ Closure or disruption of a service for less than 4 hours – managed by alternative routine procedures	**Level 4**	**Level 4**	**Level 3**	**Level 3**	**Level 2**
	Insignificant	☐ Minimal or no destruction or damage to property ☐ No effect on service	**Level 4**	**Level 4**	**Level 4**	**Level 3**	**Level 3**

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Information sources

MEAMF risk rating system

The risk rating system described here was developed using the following sources:

- Australian and international risk management standards – **AS 4360** and **ISO 31000**: *Risk management*
- Standards Australia advice on healthcare risk management – **MP 91-2000**: *Dynamic approaches to health care risk management*
- Victorian Managed Insurance Authority (VMIA) – *Risk management guide: implementing a risk management framework*
- South Australian Health Department – *Risk assessment matrix*
- ACT Health – *Asset management risk assessment matrix*
- Quality, Safety and Patient Experience Branch, Victorian Department of Health – *Incident severity rating classifications*
- Asset Management Unit, Victorian Department of Health – *Medical equipment self-prioritisation assessment package*.

C5.1 Medical equipment disposal

Purpose	To outline the relevant provisions relating to the disposal of medical equipment, including the conditions under which donations of medical equipment from third parties can be accepted.
Summary	This information sheet lists a number of references that should be considered before undertaking disposal action.
Framework references	B5.4.1 — Choose the most appropriate means of disposal B5.4.2 — Ensure disposal meets appropriate guidelines
Version 1.0, 2011	

I **Information sheet**

Medical equipment disposal

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.

General guidelines for disposal can be found at:
www.epa.vic.gov.au/about_us/legislation/epa.asp

www.vgpb.vic.gov.au/CA2575BA0001417C/pages/procurement-practitioners-stage-3---contract-management-step-6---contract-management-disposal-of-assets-policy

Guidelines for donation are available at the Engineers Australia website:
www.engineersaustralia.org.au/colleges/biomedical/advocacy/advocacy_home.cfm

X-ray equipment

Disposal of X-ray equipment can be found at:
www.health.vic.gov.au/environment/radiation/publications.htm

European Union guidance documents for special categories of waste

Batteries and accumulators
www.berr.gov.uk/whatwedo/sectors/sustainability/batteries/page30610.html

Ozone-depleting substances
www.berr.gov.uk/whatwedo/sectors/sustainability/ods/page29091.html

Packaging and packaging waste
www.berr.gov.uk/whatwedo/sectors/sustainability/packaging/page29072.html

Waste electrical and electronic equipment – the Waste Electrical and Electronic Equipment Directive (WEEE Directive) aims to minimise the impact of electrical and electronic goods on the environment by increasing re-use and recycling, and reducing the amount of WEEE going to landfill. It seeks to achieve this by making producers responsible for financing the collection, treatment and recovery of waste electrical equipment, and by obliging distributors to allow consumers to return their waste equipment free of charge.
www.berr.gov.uk/whatwedo/sectors/sustainability/weee/page30269.html

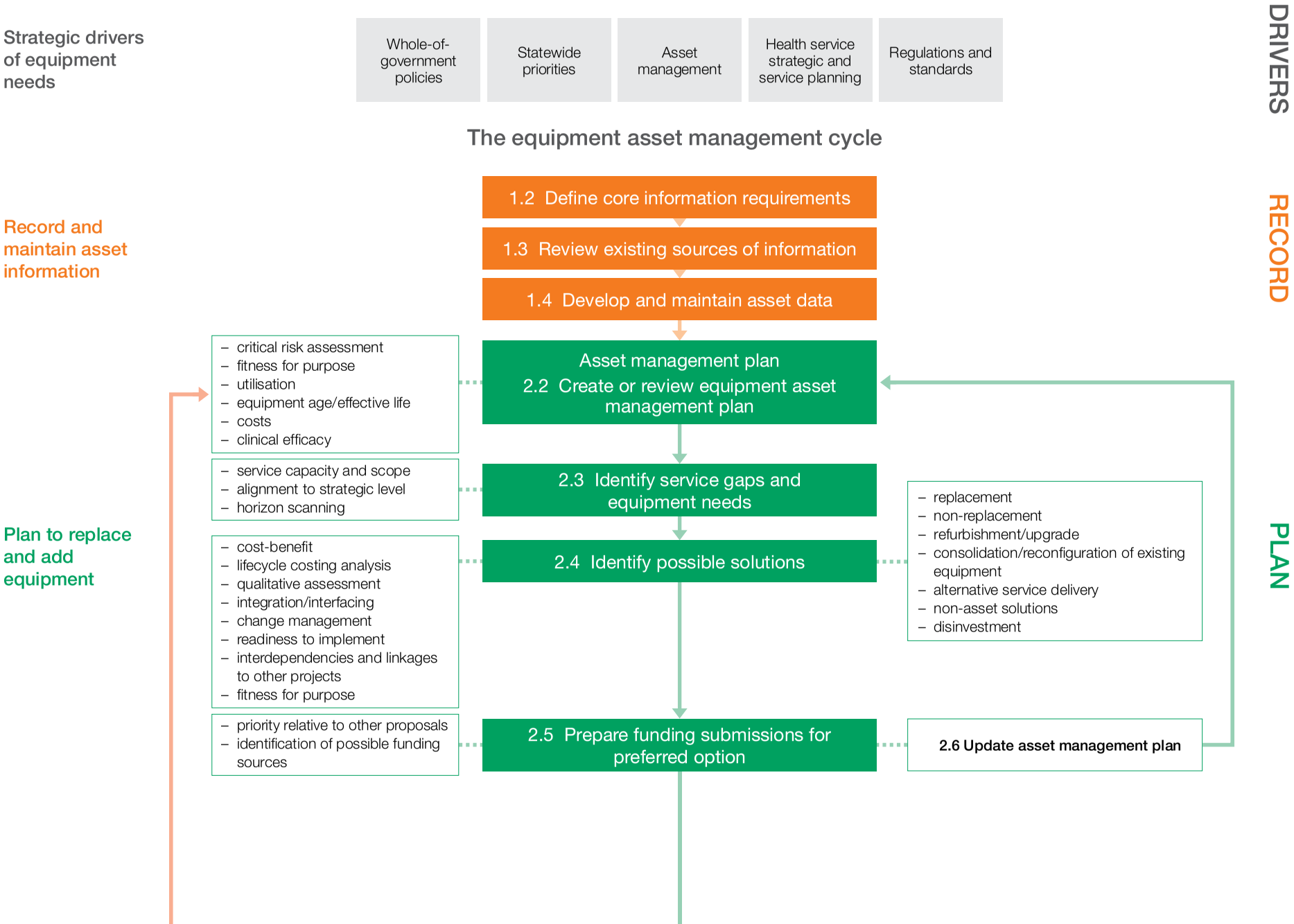
C6 Key decision points in medical equipment asset management

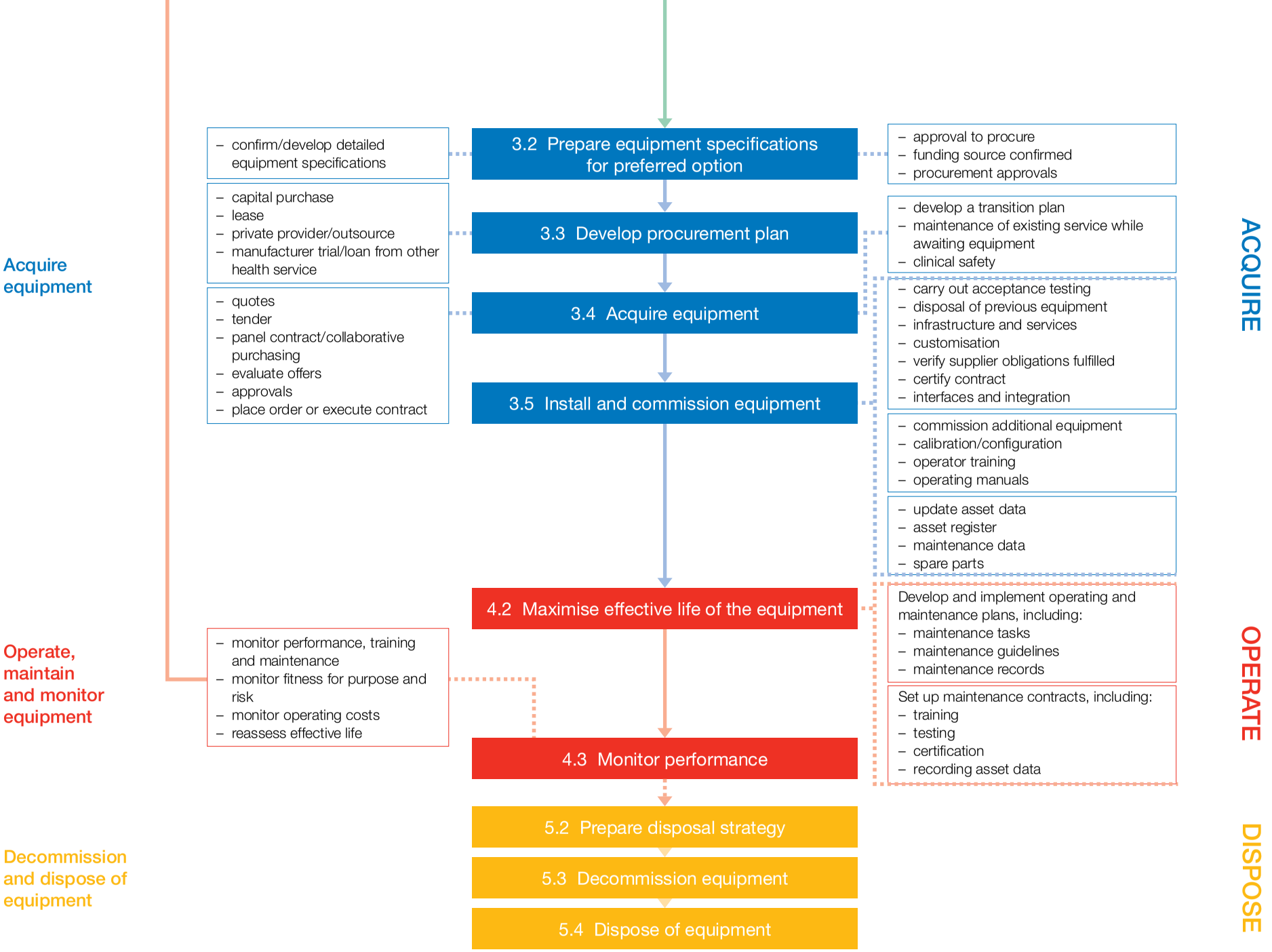
Purpose	To overview the key decision points over the lifecycle of medical equipment.
Summary	This information sheet is a summary of key decision points for medical equipment asset management. It is for practitioners.
Framework references	A — Figure A.3: Key decision points for medical equipment asset management (for executives and key decision-makers)

Version 1.0, 2011

I Information sheet

Figure 1: Key decision points in 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.

CONFIDENTIAL - Draft October 2011

Abbreviations and acronyms

ARTG	Australian Register of Therapeutic Goods
AS/NZS	Australian Standard/New Zealand Standard
CEO	chief executive officer
CPI	consumer price index
the department	Victorian Department of Health
department	department/area specific to the health service
DTF	Department of Treasury and Finance (Victoria)
EBA	enterprise bargaining agreement
GMDN	Global Medical Device Nomenclature
IEC	International Electrochemical Commission
ISO	International Organization for Standardization
IT	information technology
MEAMF	*Medical equipment asset management framework*
MHRA	Medical and Health Care Products Regulatory Agency
OHS	occupational health and safety
TCV	Treasury Corporation of Victoria
TGA	Therapeutic Goods Administration
UMDNS	Universal Medical Device Nomenclature System
WEEE	Waste Electrical and Electronic Equipment Directive
VGPB	Victorian Government Purchasing Board
WIES	Weighted inlier equivalent separation