SA Health

Guideline

Asset Management: Biomedical Technology Managing Risk

Version 1.0
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PDS Reference No: G0192

Government of South Australia
SA Health

Contents

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1. Name of guideline

Asset Management: Biomedical Technology: Managing Risk

2. Relationship to parent policy

The Asset Management Policy is the parent policy to this document, the Asset Management: Biomedical Technology: Managing Risk Guideline.

3. Guideline statement

This guideline provides a framework for controls and possible treatments to manage and mitigate risks of biomedical technology, whether by Biomedical Engineering (BME) or other parties within SA Health.

Specific information applies to that not under BME management with a method for determining assurance level required for management of biomedical technology and estimating resourcing requirements, particularly when historical records are inadequate and management shifts to an in-house biomedical technology service group.

The Biomedical Technology Guidelines support the Asset Management Policy by setting consistent practice for managing biomedical technology and medical-related devices.

These policies and guidelines on based on principles from three Standards:

- AS/NZS 3551 Management programs for medical equipment
- AS/NZS ISO 9001 Quality management systems – Requirements, and
- ISO 13485 Medical devices – Quality management systems-Requirements for regulatory processes.

SA Health applies consistent asset management principles over the asset lifecycle (acquiring, managing, maintenance and disposal) for delivery of health services and ensure assets are appropriate, available, safe, used effectively, functioning correctly, and compliant with relevant laws, regulations and standards.

4. Applicability

This guideline applies to all employees and contractors of SA Health; that is all employees and contractors of the Department for Health and Wellbeing (DHW), Local Health Networks (LHNs) including state-wide services aligned with those Networks and SA Ambulance Service (SAAS).

5. Guideline details

5.1 Risks of biomedical technology leading to adverse patient outcomes

Risks of biomedical technology in SA Health that may lead to patient harm and patient death (risk category clinical) occur when biomedical technology is not appropriate, not available, not safe, not used effectively, not functioning correctly, or not compliant with relevant laws, regulations and standards (Appendix 1: Biomedical Technology Risk Causes, Controls and Treatments) as summarised in Table 1 Risks and causes of biomedical technology leading to adverse patient outcomes.

- The main risk with biomedical technology over its lifetime that leads to the possibility of adverse patient outcomes is when it is not used correctly, due either to useability or lack of user training.

Table 1 Risks and causes of biomedical technology leading to adverse patient outcomes

Risk	Causes
1. Not used effectively	▪ Clinical useability not evaluated during acquisition, nor reassessed over lifetime (i.e., clinical performance). ▪ User training not provided initially, not available over lifetime, or not monitored for need over lifetime.
2. Not appropriate for purpose	▪ Inadequate evaluation, or not evaluated, during acquisition. ▪ Appropriateness not reassessed over lifetime
3. Not safe, not available, not functioning correctly or not compliant with relevant laws, regulations and standards	▪ Not safe – hazards, recalls or incidents not actioned ▪ Not safe - Preventative Maintenance (PM) not done, or not available over life o No plan for PM ▪ Not assessed during acquisition ▪ Not created at registration o PM not scheduled o PM overdue ▪ Not available, breakdown o Repair not timely o Unable to be repaired o Replacement overdue o PM could have prevented ▪ Not functioning correctly – PM not done (as above) ▪ Not compliant - not checked against relevant laws, regulations and standards, either during acquisition, or during lifetime.

> Risks have been separated into two parts, based on available controls:
  - Within the SA BME Management System
  - Outside the SA BME Management system

5.2 Part A: Controlled within SA BME Management System

> Risk controls and treatments should be identified in a risk assessment worksheet (Appendix 2: Risk Assessment Worksheets for Biomedical Technology).
> For a high risk (16) clinical patient device with direct contact, the controls can reduce risk to 12 (still high) and treatments could reduce risk to 8 (medium):
  - All the controls reducing risks that lead to adverse patient outcomes should be in place within SA Health and are based on the Australian context:
    - Controls within Australia and SA Health
    - Controls provided by SA BME and BME LHNs ie within SA BME Management system
> Treatments should be recommended for SA BME, BME LHN and LHN.

5.3 Controls within Australia and SA Health

Partial control of biomedical technology risks occurs with Australian regulations, and the system within which SA Health uses the biomedical technology.

- Regulations should require all medical devices used in Australia to be listed in the Australian Register of Therapeutic Goods and to be compliant with the essential principles relating to the safety and performance characteristics.
- Facilities should be designed, built, tested and maintained to Australian Standards and include patient area electrical safety requirements.
- Medical devices use should only be in patient areas with appropriate protection and wiring to AS3003 Electrical installations - Patient areas.
- Appropriate equipment used for each application should have rules linking type of procedure with class of medical device and electrical safety facilities of patient area.
- Clinicians and operators should know, not only the medical procedure, but also the safety characteristic and operational details of the biomedical technology: learning and training under supervision of the manufacturer, local representative, experienced users, or BME staff, or service entity, and recognise when not functioning correctly.
- LHN Executive who are responsible for asset management should have increasing maturity in processes for Strategic Asset Management Plans (SAMP), Asset Management Plans (AMP), biomedical technology and BME service groups.

5.4 Controls provided by SA BME Management System

The SA BME Management System should be facilitated by SA BME (DHW) and implemented by BME LHNs. It should include Guidelines, Biomedical Asset Management System (BAMS), capabilities, training and emerging risk management.

SA BME Management System

- Guidelines:
    - AMBT Lifecycle Guidelines should include processes known to reduce risks for replacement planning and acquisition, though the lifetime of maintenance to disposal.
        - Lifetime Risks controlled by AMBT Lifecycle Guidelines (Table 13).

Validation that Guidelines have AS3551 Risk Management Controls (

        - Table 14).
    - AMBT Monitoring compliance.
    - Managing contracts and contractors (procedure).
- A state-wide electronic database: BAMS:
    - Asset registration with service history over its life and all associated documents.
    - Standardised data, terminology and consistent usage (documented in BAMS Business Rules) monitored by SA BME BAMS User Group.
- Capability and training:
    - Essential criteria assessment by a professional biomedical engineer during the employment process assures they have competency, knowledge, skills and understanding required for their roles managing and maintaining biomedical technology.
    - Necessary technical training, skills and experience and ongoing development are arranged for managers, and technical staff.

Emerging risk identification and escalation

Monitoring, mitigation and escalation processes (Table 2) should be implemented when SA BME controls identify new biomedical technology risks:

- Hazards and recalls – should be:
  - monitored and actioned by LHN BME Area Manager,
  - recorded in BAMS,
  - actions allocated to LHN, and
  - monitored by SA BME DHW where state-wide strategy needed.
- Incidents should be:
  - monitored and actioned by Area, Site and Technical Managers
  - SA BME monitor for incidents that could be broader than a specific LHN.
- Safety & Quality, SABS should ensure information is shared with appropriate BME Area Managers, particularly when they are on leave or being replaced.
- Therapeutic Goods Administration (TGA) should monitor changes to regulations are monitored by SA BME DHW and shared at Leadership Committee.
- Maintenance should review:
  - No fault found - assess user training needs.
  - Excessive frequency, cost or time for maintenance - assess replacement.
  - Preventable by PM - assess changing maintenance plan (frequency or checklist).

Table 2 Risk Management: monitoring, mitigation and escalation

SA BME Committee	Membership	Table, endorse, register, mitigate and monitor risks	Escalate risk assessments
Operations	LHN BME Technical and Site Managers (or equivalent technology managers)	**Controlled** risk of MODERATE or above	Escalate **controlled** risk of HIGH
Leadership	LHN BME Area Managers (or equivalent technology manager), and SA BME Corporate	**Controlled** risk of HIGH or above	Escalate **treated** risk of HIGH
Oversight	LHN Executive nominees (responsible for LHN BME departments)	Table **treated** risk of HIGH or above	Escalate **extreme** risks to CE and CEO's

5.5 Treatments recommended

- Treatments are not in place or are partially in place and in the process of implementation.
- Recommendations should be included for both SA BME and BME LHN, and for LHN but outside SA BME responsibility.

Table 3 Recommended treatments mitigating adverse patient outcomes

Treatments SA BME	Treatments BME LHN	Treatments LHN
SA BME monitor procurement forward plan, and Tender SA to monitor appropriateness (e.g., non-standard minor equipment, consumable contracts) Include clinical performance field(s) in BAMS (appropriateness & clinical useability) SA BME develop report to monitor work with no fault found	Replacement plan includes clinical indicators: poor appropriateness, poor useability Monitor work requests where no fault found Monitor appropriateness (non-standard minor equipment) Monitor General Ledger (GL) for non-approved minor equipment purchases	LHN survey clinical users annually for: - clinical training needs - poor clinical appropriateness & useability (with results into BAMS for replacement plan)

5.6 Part B: Biomedical technology outside SA BME Management System

Risks should be borne by the responsible LHN where biomedical technology is not under BME LHN responsibility, and the SA BME Management System controls do not apply.

The main risks to the LHN responsible for the biomedical technology (Table 4) arise from inappropriate acquisition or inappropriate management (ie not registered, not maintained, or not replaced).

Table 4 Risks of Biomedical Technology when outside SA BME Management System

LHN risk	Causes
1. Inappropriate acquisition	BME Area Manager unaware of biomedical technology: ▪ Not at sites with in-house BME ▪ Prescribed for home use without BME endorsement of acquisitions ▪ Consumable contracts or lease/hire arrangements (either state-wide or by LHN Medical Department)
2. Inappropriate management – not registered - not maintained - not replaced - recalls not actioned	▪ No responsible LHN BME Area Manager or service group allocated ▪ Historically outside BME responsibility, BME Area Manager not aware, BME service group not aware of responsible service group ▪ Business units not at sites with in-house BME, or managed in-house by Clinical Department ▪ LHN/DHW BME Contract Manager not aware of maintenance and documentation requirements ▪ No nominated LHN Executive participating in Oversight Committee (responsible for BME department)

5.7 Situational risk assessment outside SA BME Management System

Biomedical Technology not under the SA BME Management System should have a risk assessment facilitated by either LHN BME Area Manager, or DHW SA BME.

> Separate risk assessments should be provided for:
  - Each situation (site, technical manager, contract manager).
  - Each type of equipment (inherent risk).

Table 5 Risk Assessment responsibility when outside SA BME Management System

Cause and LHN occurrence	**Responsibility** for identifying, developing risk assessment and recommending treatment
Biomedical technology with no on-site BME: ▪ All – Hospital at Home ▪ All – GP+, APH ▪ CALHN BSSA ▪ CALHN Prison Health ▪ Regional LHN ▪ SALHN DASSA ▪ SALHN Mental Health	Each LHN BME Area Manager: - Identify LHN sites with no on-site BME - Develop site-based risk assessment and management plan - Document management plan (in LHN AMP) and review annually
Biomedical technology historically outside LHN BME responsibility ▪ All - Med Dept prescribed patient home use (eg. CPAP) ▪ All Across Government Facilities Management Arrangements (AGFMA)	Each LHN BME Area Manager: - Identify risks for LHN - Report to LHN Executive - Share with SA BME Leadership - Facilitate LHN Contract manager understanding of risks
Technology manager equivalent to BME Area Manager: ▪ CALHN Medical Physics ▪ SA Ambulance Service (SAAS)	Technology managers and teams invited to SA BME Community of Practice: - Operations, or Leadership Committees - Trained to use BAMS for all asset registrations and service interventions
BME Area Manager unaware of biomedical technology: ▪ Consumable contracts ▪ Leased/hire arrangements ▪ Minor equipment (e.g., for patient home use)	Identify acquisitions and register assets and service support on BAMS: - LHN BME Area Manager monitor LHN GL Minor Equipment purchases - DHW SA BME monitor TenderSA website for SA Health procurements to be tabled at SA BME Leadership Committee
No single BME Area Manager responsible: ▪ CALHN (SCSS): SAMI ▪ CALHN (SCSS): SA Pharmacy ▪ CALHN (SCSS): BSSA	Identify where no responsible LHN BME Area Manager, or non-BME technical manager: - DHW SA BME, report to SA BME Oversight Committee
No LHN Executive nominee at SA BME Oversight Committee ▪ SAAS	DHW SA BME assess risk and report to SA BME Oversight Committee for discussion of SA Health implication and appropriate action

Cause and LHN occurrence	**Responsibility** for identifying, developing risk assessment and recommending treatment
TGA-defined medical devices that are excluded from BME-managed biomedical technology ▪ Surgical implants ▪ Allied Health medical device custom manufacture ▪ Allied Health mobility aides and rehabilitation	TGA requirement for responsible group (e.g., Clinical Department) to track items, recalls and actions: device use, location (may include patient data), custom device raw materials etc.

Note: Some Medical Departments/Business Units can be identified in multiple rows.

Identify non-BME managed biomedical technology

> At a minimum, where there is no evidence to support that biomedical technology is managed consistently with AS3551:
    - BME LHN should escalate risk to their responsible LHN Executive.
    - Where no BME or LHN Executive is responsible, SA BME DHW should escalate risk to SA BME Oversight Committee.

> Biomedical technology and its inherent risk should be confirmed:
    - Some medical-related devices can benefit from AS3551-consistent management.
    - Determine inherent risk rating: Appendix 4: Inherent Risk Rating for Biomedical Technology eg Low risk for Class II or battery-operated with Inherent risk of 1.
        - Refer SA BME BAMS User Guide and Business Rules, Section 14.4 Risk.

> A situational risk assessment worksheet should be developed:
    - Use drafts in Appendix 5: Situational Risk for Biomedical Technology outside BME Management.
    - Describe controls (in place) and treatments (proposed).
    - Adjust controlled risk rating and treated risk rating.
    - An appropriate treatment is to provide a level of BME assurance with annual review.

> Risk assessment worksheet/s should be discussed with LHN Executive responsible for LHN BME:
    - Confirm risk ratings.
    - If risk rating High or Extreme, LHN should add to their risk register until controlled.
    - Managers of the technology should also be reporting to a similar LHN Executive.
    - Determine treatment plan if needed to mitigate risk further, including:
        - Registration on BAMS (generic asset or individual assets).
        - Transfer to BME responsibility.
        - Annual BME assurance of management.
        - BME advice to regular contract management review meetings.

Assess an appropriate level of BME assurance

> BME assurance should be provided, particularly for biomedical technology with High (16) or Moderate (9) risk, considering:
    - Inherent risk of the biomedical technology.
    - Risk remaining with LHN.

- Effectiveness of Contract Manager (LHN or SA Health):
  - Assigned contract manager level of technical knowledge.
  - Service contract provision by an appropriate service provider.
  - Acquired within a consumable contract or lease arrangement.
- Need for BME management:
  - Replacement plan (needs asset registration).
  - BME action for hazards, recalls and incidents (needs asset registration).
  - Accessible service history (needs asset registration).
  - Asset registration for each asset, or generic for group of assets (low risk only).
- Need for a maintenance plan to meet requirements for legislation, regulation, manufacturer or historical experience within SA BME.

> To assess requirement, should refer to the guide in Appendix 6: BME Assurance with Resource Estimate.

Table 6 Controls and treatments for Biomedical Technology with non-BME management

BME LHN not responsible Not represented at Oversight	Comment Assurance	Asset register	Community of Practice, CoP	SA BME Oversight
AGFMA managed equipment	Transfer to LHN BME management, or BME provide a level of assurance while under AGFMA	None	N/A	N/A (AGFMA FMGG)
CALHN Medical Physics (Radiation Oncology) – complex high risk, high value biomedical technology	Technology manager (BME equivalent) invited to SA BME CoP	BAMS	1,2	
DASSA - minimal low risk equipment under service contract	Assurance by SALHN BME: contracted maintenance service, small number of low-risk assets Not in replacement plan	Excel	N/A	SALHN
Mental Health	Assurance by SALHN BME: contracted maintenance service, small number of low-risk assets Not in replacement plan			SALHN
SAAS & MedStar – minimal low risk equipment managed in-house	Technology manager (BME equivalent)	SAAS Excel	1,2	N/A
SCSS:	No responsible BME manager	BAMS		SCSS Dir Finance
▪ BSSA – Complex biomedical technology mainly under contract	No responsible BME manager	BAMS if advised		SCSS Dir Finance
▪ SAMI – Highly complex and high value biomedical technology, largely under service contract	Use LHN BME Manager at each site No single BME Area Manager responsible Technology manager (non-BME) invited to CoP	BAMS if advised	1,2	SCSS Dir Finance

BME LHN not responsible Not represented at Oversight	Comment Assurance	Asset register	Community of Practice, CoP	SA BME Oversight
▪ SA Pharmacy – minimal equipment, low risk	Use LHN BME Manager at each site	BAMS if advised		SCSS Dir Finance
▪ SA Pathology CTL	Technology manager (BME equivalent) invited to CoP	BAMS	1,2	SCSS Dir Finance

Legend: CoP 1: SA BME Operations Committee & Community of Practice (formed 2021);
CoP 2: Invited as member of SA BME Leadership Committee & Community of Practice (formed 2021).

6. Supporting information

- Asset Management Policy
- Asset Management: Biomedical Technology Lifecycle Guideline Part 1 Planning and Acquisition
- Asset Management: Biomedical Technology Lifecycle Guideline Part 2 Acceptance to Disposal
- Asset Management: Biomedical Technology Maintenance Planning Policy
- Asset Management: Property, Plant and Equipment Lifecycle Guideline
- SA BME Purpose & Value Statement (PDF 325KB)

7. Definitions

- **Across Government Facilities Management Arrangements (AGFMA)** means agreement by which facilities are managed across SA Government agencies, responsibility of Department for Infrastructure and Transport (DIT).
- **Asset Management Plan (AMP)** means documented information, updated 2 yearly that specifies the asset performance, activities/projects, resources and timescales required for an individual asset or a grouping of assets, to achieve the organisation's asset management objectives.
- **Biomedical Asset Management System (BAMS)** means a database comprising a record for each item of biomedical technology to provide evidence of adequate and effective operation of the biomedical technology management program.
- **Biomedical technology management group (BME)** means departments and people that provide biomedical technology management and maintenance services to SA Health and participate in the SA BME Governance and Community of Practice.
- **Biomedical technology** means any electronic, electro-mechanical, mechanical, optical or pneumatic instrument, device, equipment, apparatus, or appliance (whether used alone or in combination, and including the software necessary for its proper application) intended, by the assigned SA Health manager, to be used either in-vitro or in-vivo for human beings for the purpose of, or research into, one or more of the following:
    - diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease
    - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
    - investigation, replacement or modification of the anatomy or of a physiological process, or pathological process, or
    - control or support of conception, and
    - that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which that may be assisted in its function by such means, or
    - an accessory to such an instrument, device, equipment, apparatus, or appliance or devices intended for disinfecting another medical device.

Any device, instrument, apparatus, accessory or consumable attached to the item of biomedical technology whether by direct or indirect (eg wireless connection) means is to be considered part of the biomedical technology.

The Manager BME should maintain a list of biomedical technology that is either exempt from this policy or included where such inclusion was either considered to be ambiguous or subject to a specific determination.

- **Biomedical Engineering (BME) LHN** means the Departments within SA Health LHN that are part of the SA BME Community of Practice implementing Asset Management Policies and Guidelines and participates in three levels of SA BME Committees: strategic (Oversight), tactical (Leadership), and operational (Operations).
- **Consumable** means part of the biomedical technology that is replaced after patient use.
- **Medical-related devices** means those that subject to BME LHN approval, benefit from management to AS3551.
- **Performance Verification (PV)** means testing the essential performance parameters of the biomedical technology. This will require a range of physical, functional and electrical tests to confirm it is capable of performing safely and as intended by the manufacturer.
- **Preventive Maintenance (PM)** means maintenance carried out at predetermined intervals, or according to prescribed criteria, and intended to reduce the probability of failure or the degradation of the functioning of an item.
  PM is intentionally designed to exclude routine testing or PV that, whilst it may confirm function at a certain point in time, does nothing to reduce the probability of failure.
- **SA Health and medical department managers** means SA Health staff with the responsibility of using biomedical technology within their clinical departments.
- **South Australia Biomedical Engineering (SA BME)** means a statewide Community of Practice that sets the standard for managing SA Health's biomedical technology and facilitates statewide SA Health meetings at three levels: Oversight, Leadership and Operations.
- **State-wide services** means State-wide Clinical Support Services, Prison Health, SA Dental Service, BreastScreen SA and any other state-wide services that fall under the governance of the Local Health Networks.
- **Strategic Asset Management Plan (SAMP)** means documented information updated at least every five years. That specifies and identifies an organisation's asset management objectives, strategic infrastructure / asset risk and strategic priorities to meet organisational objectives.

8. Document ownership

Guideline owner: Domain Custodian for the Infrastructure and Asset Management Domain

Title: Asset Management: Biomedical Technology Managing Risk Guideline

Objective reference number: A5262548

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Contact for enquiries: Health:SA BME Corporate

9. Document history

Version	Date approved	Approved by	Amendment notes
1.0	03/12/2023	Chief Executive, DHW	New guideline to reflect current practice

10. Appendices

1. Biomedical Technology Risk Causes, Controls and Treatments
2. Risk Assessment Worksheets for Biomedical Technology
3. Controls for Risk Management
4. Inherent Risk Rating for Biomedical Technology
5. Situational Risk for Biomedical Technology outside BME Management
6. BME Assurance with Resource Estimate
7. Contract Advisory Service Detail
8. Transfer of Biomedical Technology to Management by BME
9. Benchmark BME Time, CoSR and CoCR

Appendix 1: Biomedical Technology Risk Causes, Controls and Treatments

Causes of risks and their controls and treatments to assure equipment is appropriate, available, safe, used effectively, functioning correctly or compliant with laws, regulations or standards.

Table 7 Risk Assessment – Biomedical Technology not used effectively

Causes	Control & Treatment description	Guideline/Policy
1. Clinical useability not evaluated during acquisition, or reassessed over lifetime		
Control	Acquisition includes evaluation of clinical useability BME LHN replacement plan includes clinical useability	AMBT Pt1, 5.2.2 AMBT Pt1, 5.1.3
Treatment	LHN survey clinical users annually for clinical useability	AMBT Pt2, 5.5.11
Treatment	Results stored in BAMS and identified in replacement plan	AMBT Pt1, 5.1.2
2. User training - not provided initially, not available over lifetime, not monitored for need over lifetime		
Control	Acquisition process includes evaluation of user training: initial, and available over lifetime	AMBT Pt1, 5.2.2 AMBT Pt2, 5.5.11
Control	Monitor SLS for medical device incidents that could have been avoided with user training	AMBT Pt2, 5.5.9
Treatment	LHN survey clinical users annually for training needs	AMBT Pt2, 5.5.11
Treatment	BME LHN monitor work requests where no fault found for possible user training need	AMBT Pt2, 5.5.3
Treatment	SA BME analyse “no fault found” work requests	AMBT Monitor

Table 8 Risk Assessment – Biomedical Technology not appropriate for proposed use

Causes	Control & Treatment description	Link to Guidelines
1. Appropriateness not evaluated at acquisition		
Control	Acquisition process: includes BME evaluation; compliance; clinical and technical appropriateness; maintainability over life; and clinical appropriateness.	AMBT Pt1, 5.2.2
Treatment	LHN BME monitor clinical appropriateness (alignment with LHN standard for clinical purpose with user training, consumables, accessories, spare parts) - Monitor GL for Minor Equipment purchases	AMBT Monitor
Treatment	SA BME monitor equipment acquired without BME advice - Procurement forward plan - Tender SA Health procurements	AMBT Monitor
2. Appropriateness not reassessed over lifetime		
Control	SA BME BAMS has clinical performance field for BME LHN replacement plan	AMBT Pt2, 5.5.11
Treatment	LHN survey clinical users annually BME hold results in BAMS for replacement plan**Error! Bookmark not defined.**	AMBT Pt2, 5.5.11

Abbreviations:

AMBT Pt1/Pt2: Asset Management: Biomedical Technology Lifecycle Guideline (Parts 1 & 2);

AMBT Monitor: Asset Management: Biomedical Technology Monitoring Compliance Guideline (Pending).

Table 9 Risk Assessment – Biomedical Technology not available, not safe, not functioning correctly, or not compliant

Causes	Control & Treatment description	Guideline/Policy
1. Not safe - hazards, recalls, incidents not actioned		
Control	LHN BME actions hazards and recalls in timely manner	AMBT Pt2, 5.5.10
Control	LHN BME receives, monitors and actions SLA incidents	AMBT Pt2, 5.5.10
Treatment	LHN BME monitor SABS and TGA hazard and recalls	AMBT Pt2, 5.5.11
Treatment	SA BME monitors TGA notices and changes to legislation	AMBT Pt2, 5.5.9
2. Not safe – PM not done: no plan for PM, not scheduled, or PM not completed.		
Control	Asset registration includes maintenance plan and schedule	AMBT Pt2, 5.4.3 AMBT Maint Plan
Control	LHN BME monitor PM not done (KPI3 & 3b): PM completed in month, not under PM (no schedule), and PM overdue	AMBT Monitor
Treatment	SA BME escalation for new (or all) assets: PM not done (no maintenance plan, no maintenance schedule, or PM not done	AMBT Monitor
3. Not safe – PM not available over life, not assessed at acquisition, or not supportable		
Control	LHN BME evaluate lifetime maintenance at acquisition: supplier support over life, and provision of technical training	AMBT Pt1, 5.2.2
Control	SA BME expert advice to statewide procurement evaluations: - consumable contracts, lease or hire agreements - minor equipment	AMBT Pt1, 5.2.2 AMBT Pt1, 5.2.3
Control	LHN BME endorse minor equipment purchases - align with LHN standard for clinical purpose including user training, consumables, accessories, spare parts and technical support	AMBT Pt1, 5.2.2
Treatment	Monitor Minor Equipment-BME purchases in General Ledger	AMBT Monitor
Treatment	LHN BME evaluate changes to lifetime maintenance needs	AMBT Pt2, 5.5.7
4. Not available - breakdown: repair not timely, not repairable, replacement overdue, preventable		
Control	LHN BME prioritise repairs and return to users preferably same day	AMBT Pt2, 5.5.2 AMBT Pt2, 5.5.5
Control	SA BME monitor KPI Corrective maintenance (1 & 1c) - Repairs within 1 day (or 7 days regional) - Repairs >30 days, >90 days	AMBT Monitor
Control	Replacement plan: obsolete (supplier advice), high repair cost or time, unable to repair	AMBT Pt1, 5.1.3
Control	BME LHN review repairs flagged as PM preventable	AMBT Pt2, 5.5.7
Treatment	LHN BME monitor repair times, long and expensive repairs	AMBT Monitor
5. Not functioning correctly – Not safe (as above) or maintenance not available (as above)		
6. Compliance not checked against relevant laws, regulations and standards: acquisition, over life		
Control	Acquisition evaluation includes compliance check	AMBT Pt1, 5.2.2
Control	SA BME & BME LHN action hazards and recalls	AMBT Pt2, 5.2.7
Control	Replacement plans include non-compliant	AMBT Pt1, 5.1.3
Treatment	SA BME monitor changes to relevant laws, regulations and standards over lifetime, and monitor TGA news Maintenance Review includes changes to compliance	AMBT Pt2, 5.5.9

Abbreviations:

AMBT Pt1 & 2: Asset Management: Biomedical Technology Lifecycle Guideline; BT biomedical technology

AMBT Maint Plan: Asset Management: Biomedical Technology Maintenance Planning Policy

AMBT Monitor: Asset Management: Biomedical Technology Monitoring Compliance Guideline

Appendix 2: Risk Assessment Worksheets for Biomedical Technology

The risk assessments for biomedical technology are separated into three based on their independent controls and treatments:

a) Not used effectively.
b) Not appropriate.
c) Not safe, not available, not functioning or not compliant.

They are for biomedical technology with a starting (inherent) high risk (16), typical for a patient critical device, that within a month of a scheduled intervention not occurring, would be highly likely for a major consequence (such as a clinical event causing serious injury).

Table 10 Risk Assessment - Biomedical Technology used effectively

RISK ASSESSMENT – Biomedical technology used effectively			
Organisation/Div:	**SA Health: SA BME, Infrastructure & all LHN's**	Link to SA Health Risk Assessment Matrix	
		Inherent Risk Rating	High (16)*2 depends on device
Assessment Group:	**SA BME Leadership Committee**		
Date:	**XX July 2021**	Consequence Level: Major	Likelihood Level: Likely
Objective: *Strategic or business objective that will not be achieved?*	**Safety & Quality and our Consumers** **Risk category: Asset & Facility Management**	**Controlled Risk Rating**	High (12)*2 depends on device
Risk Title:	**Biomedical Technology not used effectively**	Consequence Level: Major	Likelihood Level: Possible
Description: *Event-cause-consequence*	Biomedical technology with poor useability, or incorrect use, may lead to patient harm and patient death	**Treated Risk Rating**	Medium (8)*2 depends on device
Context: *Describe the scope and context of the risk*	Biomedical technology for delivery of health services in SA Health are **used effectively** over the asset lifecycle. Assure useability for clinical outcomes in a healthcare setting: useability testing at acquisition, and user training, should have prominence over lifetime failure, as user error is a much greater issue for patient safety than technical failure.*1	Consequence Level: Major	Likelihood Level: Unlikely
		Primary Consequence Type	Clinical

Causes *Key factors contributing to risk occurring*	**Consequences** *Primary impacts should the risk occur*	**Controls** *Key activities performed now that reduce the risk*	**Treatments** *Key future actions planned to further reduce the risk*
Useability • Not evaluated at acquisition • Not reassessed over lifetime User training • Not provided initially • Not available during lifetime	Patient harm due to ineffective use	During acquisition: • Evaluate clinical useability • Acquire initial user training • Identify follow-up training availability BME LHN monitor SLS for user training needs Replacement plan (BME) has clinical performance (useability) Medical Dept monitor user training and arrange	Over lifetime: • BME monitor equipment failures where no fault found as indicator of possible user-training need • Monitor clinical useability o LHN survey users o BME add to BAMS

APPROVED BY: Anne-Louise Smith, Director SA BME and Asset Management, Chair SA BME Oversight Committee **DATE:**

*1 AS3551 Management programs for medical equipment

*2 Worksheet for biomedical technology with inherent risk of high (16)

Table 11 Risk Assessment - Biomedical Technology: appropriate

RISK ASSESSMENT – Biomedical technology appropriate							
Organisation/Div:	**SA Health: SA BME, Infrastructure & all LHN's**			Link to SA Health Risk Assessment Matrix			
Assessment Group:	**SA BME Leadership Committee**			**Inherent Risk Rating**		High (16)*2 depends on device	
Date:	**August 2021**			Consequence Level	Major	Likelihood Level	Likely
Objective: *Strategic or business objective that will not be achieved?*	**Safety & Quality and our Consumers** **Risk category: Asset & Facility Management**			**Controlled Risk Rating**		High (12)*2 depends on device	
Risk Title:	**Biomedical Technology not appropriate**			Consequence Level	Major	Likelihood Level	Possible
Description: *Event-cause-consequence*	Biomedical technology that is not appropriate for clinical purpose, may lead to patient harm and patient death			**Treated Risk Rating**		Medium (8)*2 depends on device	
Context: *Describe the scope and context of the risk*	Biomedical technology for delivery of health services in SA Health are **appropriate for use** over the asset lifecycle. Assure appropriateness of the technology for jurisdictional compliance and clinical outcomes in a healthcare setting, and that is remains appropriate over lifetime.*1			Consequence Level	Major	Likelihood Level	Unlikely
				Primary Consequence Type		Clinical	
Causes *Key factors contributing to the risk occurring*	**Consequences** *Primary impacts should the risk occur*	**Controls** *Key activities performed now that reduce the risk*	**Treatments** *Key future actions planned to further reduce the risk*				

Inadequate evaluation at acquisition:
• TGA not approved
• Clinical use
• Known hazards not identified
• No BME endorsement
Change in clinical requirements over lifetime
	Patient harm due to equipment:
	• Not compliant
	• Not fit for clinical purpose
	• Having known hazards
	• Non-standard (no spare parts, accessories and consumables; no manuals, no technical support)
		During acquisition confirm:
		• Compliance
		• Appropriateness (clinical and technical), hazards controls
		• Maintainability over life
		• BME endorsement in procurement process templates
		Replacement plan (BME) has clinical performance (appropriate)
			Over lifetime:
			• Monitor clinical appropriateness
			  ○ Medical Dept monitor SLS
			  ○ LHN survey users
			  ○ BME add to BAMS
			• BME monitor non-endorsed minor equipment purchased
			• SA BME monitor procurement forward plans & Tender SA				

APPROVED BY: Anne-Louise Smith, Director SA BME and Asset Management, Chair SA BME Oversight Committee **DATE:**

*1AS3551 Management programs for medical equipment

*2Worksheet based on biomedical technology with inherent risk of high (16)

Table 12 Risk Assessment - Biomedical Technology: safe, available, functioning correctly and compliant

RISK ASSESSMENT – Biomedical technology safe, available, functioning correctly and compliant							
Organisation/Div:	**SA Health: SA BME, Infrastructure & all LHN's**			Link to SA Health Risk Assessment Matrix			
Assessment Group:	**SA BME Leadership Committee**			**Inherent Risk Rating**		High (16)*2 depends on device	
Date:	**XX July 2021**			Consequence Level	Major	Likelihood Level	Likely
Objective: *Strategic or business objective that will not be achieved?*	**Safety & Quality and our Consumers** **Risk category: Asset & Facility Management**			**Controlled Risk Rating**		High (12)*2 depends on device	
Risk Title:	**Biomedical Technology not safe, not available, not functioning correctly or not compliant**			Consequence Level	Major	Likelihood Level	Possible
Description: *Event-cause-consequence*	Biomedical technology that is not safe, available, functioning correctly, and compliant, may lead to patient harm and patient death			**Treated Risk Rating**		Medium (8)*2 depends on device	
Context: *Describe the scope and context of the risk*	Biomedical technology for delivery of health services in SA Health are **safe, available, functioning correctly, and compliant** over the asset lifecycle. A system of maintenance (PM) assures the operational state continues.*1 Priority for PM to identify failure due to component wear, over PV (operation continues until random failure causes breakdown).*1			Consequence Level	Major	Likelihood Level	Unlikely
				Primary Consequence Type		Clinical	
Causes *Key factors contributing to risk*	**Consequences** *Primary impacts should risk occur*	**Controls** *Key activities performed now that reduce the risk*	**Treatments** *Key future actions planned to further reduce the risk*				
• Not safe, not maintained • Not available (breakdown) • Not functioning correctly • Not compliant	Patient harm due to equipment failure.	Check safety and functioning correctly • Hazards, recalls and incidents prioritised & timely • PM: plan, schedule and monitor, include minor eqpt and consumable contracts Not available: • Repair breakdown: prioritised & timely • Replacement plan (obsolete; high repair frequency, cost or time; unable to repair; non-compliant) • Check if PM could have prevented Check compliant: acquisition, and over life (Maintenance review)	Escalate PM outliers (not assessed, planned, scheduled or done) Over lifetime: • Review repairs, SLS, and non-compliance for changes to maintenance plan • Monitor changes to compliance (TGA & regulations)				

APPROVED BY: Anne-Louise Smith, Director SA BME and Asset Management, Chair SA BME Oversight Committee **DATE:**

*1AS3551 Management programs for medical equipment; PM, preventive maintenance; PV, performance verification.

*2Worksheet for biomedical technology with inherent risk of high (16)

Appendix 3: Controls for Risk Management

Controls for risk management are included in the Asset Management: Biomedical Technology (AMBT) Lifecycle Guidelines:

- Lifetime risks (Table 13).

Risk management controls required by AS3551 (validation in

- Table 14).

Table 13 Lifetime Risks controlled by AMBT Lifecycle Guidelines

Before clinical use	During lifetime
Replacement planning Acquisition: purchases Australian Register of Therapeutic Goods (ARTG) listed, under standard Terms and Conditions (not limited to Purchase Order Terms and Conditions), maintenance over life or technical training included, standardised (to match technical knowledge, consumables, or parts availability) Acceptance tested before clinical use Asset registered Maintenance plans assessed and independently reviewed External service providers, contractors and contract managed	Scheduled maintenance monitored and reviewed for emerging risks Test equipment maintenance planned Maintained with reference to manufacturer's instruction using formal risk analysis within a risk management framework Routine performance verification during useable life to detect damage, wear, component failure, or changed component value which may render it unsafe Lifetime records linked to assets (maintenance, configuration, service reports, and maintenance review) Hazards, recalls and incidents: actioned and documented, SLS directed to technology manager Disposal, removal or transfer: assessed for safety, patient data removed
Monitoring and reporting	**Leadership Review and KPI**
Maintenance plan and schedules Maintenance scheduled or performed Maintenance review over life Hazards, recalls and incidents identified, monitored or actioned	Asset registration includes maintenance plan, acceptance checklist, and schedule. PM completed, outstanding, not under PM Not in replacement plan Repair completion timely Repair time outlier analysis

Table 14 Validation that Guidelines have AS3551 Risk Management Controls

Risk management requirement from AS3551 (Appendix A2)	Guideline
1. Technology assessment	
> Assess suitability of the technology for use in a healthcare setting from a clinical outcome balanced against funding issues.	AMBT Pt1, 5.2.2
2. Technology manufacture	
> Manufacturers in Australia are required to have Quality Management Systems which complies with AS13485, and usually also IEC60601-1 > Applies where development or modification causes BME to become manufacturer	AMBT Pt1, 5.2.1 & 5.2.2 AMBT Pt2, 5.5.4
3. Technology acquisition	
> During acquisition, note hazards involved with use of BT and the usual methods to control those hazards. Purchasing evaluation that considers all hazards will demonstrate care in process. > Useability testing should have prominence over lifetime failure, as user error is a much greater issue for patient safety.	AMBT Pt1, 5.2.2 AMBT Pt1, 5.2.2
4. Incoming installation, commissioning and acceptance	
> Ensure new BT is safe and performing as intended before patient use > A suitable system of maintenance assures the operational state continues. > Ensure operators have initial and follow-up training as user has a much greater impact on patient safety than failure during use.	AMBT Pt2, 5.4.4 AMBT Pt2, 5.4.3 AMBT Pt1, 5.4.2
5. Initial PV test selection (where no local failure data)	
> Implement PV and PM according to manufacturer's recommendation where there is no history. > Emphasis on inspecting safety features or interlocks whose function users cannot readily detect during normal operation. > Major effort working out critical failure areas so maintenance records can collect failure data to adjust maintenance program	AMBT Pt2, 5.4.3 AMBT Pt2, 5.4.4 AMBT Pt2, 5.5.2
6. Review of PV test selection (failure data since initial acquisition)	
> Review in-service testing data to see level of non-user detectable faults discovered and review failure and incident data that did or could have caused major consequences. Gives objective level of confidence that BT is operating correctly, and in-built safety features are working.	AMBT Pt2, 5.5.7
7. Post-repair PV inspection	
> Extensively test area involved in repair to ensure the BT meets all performance requirements and all safety features are operational and accurate. Best to follow manufacturers test process.	AMBT Pt2, 5.5.3
8. Prioritisation of PM program and PV program	
> PM and inspection programs should be managed separately: - if PM is not performed, BT will fail due to component wear - if PV is not performed, BT will continue to work until random failure causes breakdown, however, may have uncalibrated operation, or unverified where legislative compliance needed > Prioritisation based on BT purpose, risk and overdue period. High risk items greatly overdue are escalated in priority.	AMBT Pt2, 5.4.3 AMBT Pt2, 5.5.6 AMBT Pt2, 5.5.6
9. Modification and use of non-OEM spare parts	
> Use risk management techniques similar to original design and manufacturing process (FMEA or RPN type systems)	AMBT Pt2, 5.5.4
10. Risk management throughout BT clinical life	
> Deviation from manufacturers specifications > Scheduled maintenance plan (manufacturer recommended or changed) > Adequate documentation to support an audit of the lifecycle management process and communication to responsible organisation	AMBT Pt2, 5.5.4 AMBT Pt2, 5.4.3 & 5.5.7 AM Policy

AMBT Pt1&2: Asset Management: Biomedical Technology Lifecycle Guideline; BT biomedical technology

Appendix 4: Inherent Risk Rating for Biomedical Technology

Table 15 Inherent Risk Rating for Biomedical Technology

Risk Consequence & likelihood		Business or clinical impact to organisation If asset was unavailable, uncalibrated or unsafe because of SA BME actions (or in-actions)	Example
25 Extreme CATASTROPHIC & ALMOST CERTAIN		If a category of biomedical technology existed where, inherently, a **consequence of fatality was almost certain** if SA BME controls or treatments fail, the device should never be put into service	Only applies to newly installed or modified Medical Gas Systems until they are tested and commissioned to AS2896
16 High MAJOR & LIKELY		**Within a month** of a scheduled intervention not occurring it would be highly likely to be a **major consequence** such as: - a clinical event causing serious injury, - a financial loss > $5 mill, - the serious permanent injury of a staff member, - a major failure for non-compliance with regulations, - a major impact on the delivery of core services, or - on-going widespread negative media impact on the organisation.	Applies to 1.8% biomedical technology Patient critical devices (e.g. life support equipment, surgical lasers, ventilators).
9 Medium MODERATE & POSSIBLE		**Within a year** of a scheduled intervention not occurring it would be possible for the organisation to suffer a **moderate consequence** such as: - a clinical event causing a temporary injury, - a financial loss > $1mill, - serious temporary injury to a staff member, - repeated citing for regulatory non-compliance, - a moderate disruption to the delivery of core services, or - repeated response to negative media impact on the organisation.	Applies to 18% biomedical technology Clinical devices with direct patient connections, direct patient diagnosis equipment, energy delivering devices (eg X-Ray), water quality systems, sterilisers, blood refrigerators etc.
4 Low MINOR & UNLIKELY		**Within 5 years** of a scheduled intervention not occurring it would be **unlikely** to be a consequence such as: - a clinical event causing a short term injury, - a financial loss > $250 thousand, - short term lost time by a staff member, - once-off regulatory non-compliance reported without penalty, - a short disruption to the delivery of core services, or, - isolated negative media impact on the organisation	Applies to 62%, most biomedical technology Clinical devices with no direct patient connections, general laboratory equipment, dental equipment, etc.
1 Negligible INSIGNIFICANT & RARE		**Within 10 years** of a scheduled intervention not occurring it would be **rare** for even minimal consequences including: - any clinical event causing any injury, - any financial loss, any lost time by a staff member, - immaterial regulatory non-compliance reported, - negligible short disruption to delivery of core services, - any negative media impact on the organisation.	Applies to 19% biomedical technology Domestic appliances, ICT equipment, non-mains connected clinical, laboratory and dental equipment.

Appendix 5: Situational Risk for Biomedical Technology outside BME Management

Two draft situational risk assessments with independent controls and treatments for biomedical technology management or replacement outside SA BME Management System.

Table 16 Risk Assessment - Biomedical Technology outside SA BME management

RISK ASSESSMENT – Biomedical Technology outside SA BME management					
Organisation/Division	**SA Health/DHW/Infrastructure & all LHN's**	Click for the SA Health Risk Assessment Matrix			
		Inherent Risk Rating	High (12)** depends on device		
Assessment Group:	**SA BME Leadership Committee**	Consequence Level	Major	Likelihood Level	Possible
Date:	**7/5/2021**	**Controlled Risk Rating**	High (12))** depends on device		
Objective: *Strategic or business objective that will not be achieved?*	**Safety & Quality of Services** **Risk Category: Asset & Facility Management, Clinical**	Consequence Level	Major	Likelihood Level	Possible
Risk Title:	**Biomedical Technology Management not under SA BME**	**Treated Risk Rating**	Moderate (8))** depends on device		
Description: *Event-cause-consequence*	Unsafe biomedical technology due to poor management (not under SA BME) may lead to patient harm and patient deaths	Consequence Level	Major	Likelihood Level	Unlikely
Context: *Describe the scope and context of the risk*	**Biomedical technology can become hazardous and requires careful management.** SA BME provides a system of controls to assure biomedical technology is managed to AS3551 so it stays safe and functional over its lifetime. E.g. unique asset registration on Biomedical Asset Management System (BAMS); commissioning; risk assessment; maintenance plan; technical expertise; hazards, recalls and incident actions; and all associated documentation kept.	**Primary Consequence Type**	Clinical		

Causes *Key factors contributing to the risk occurring*	**Consequences** *Primary impacts should the risk occur*	**Controls** *Key activities performed now that reduce the risk*	**Treatments** *Key future actions planned to further reduce the risk*

Management:
• not to AS3551
• Records of registration, maintenance, hazards and incidents not kept or monitored
Maintenance:
• not scheduled
• by untrained personnel
	Patient harm due to:
	• Poor or inappropriate maintenance
	• Inappropriate schedule or checklist
	• Inappropriate technical expertise
	• Inappropriate review of maintenance plans
		(Move to treatment if they do not cover all biomedical technology)
		• Asset Management: Property, Plant and Equipment Lifecycle Policy Directive
		• Asset Management: Biomedical Technology Guidelines
			Develop LHN plan with resources to:
			• Register all biomedical technology
			• Validate condition & compliance
			• BME (LHN) oversight of:
			  ○ Maintenance plan (schedule, checklist & personnel)
			  ○ Actions for hazards, recalls, and incidents

APPROVED BY: Anne-Louise Smith, Director SA BME and Asset Management **DATE: 7/5/2021**

Table 17 Risk Assessment - Biomedical Technology replacement plan outside LHN BME

RISK ASSESSMENT – Biomedical Technology replacement plan outside BME					
Organisation/Division	**SA Health/DHA/Infrastructure and all LHN's**	SA Health Risk Assessment Matrix			
		Inherent Risk Rating	High (12))** depends on device		
Assessment Group:	**SA BME Leadership Committee**	Consequence Level	Major	Likelihood Level	Possible
Date:	**7/5/2021**	**Controlled Risk Rating**	High (12))** depends on device		
Objective: *Strategic or business objective that will not be achieved?*	**Safety & Quality of Services** **Risk Category: Asset & Facility Management, Clinical**	Consequence Level	Major	Likelihood Level	Possible
Risk Title:	**Biomedical technology replacement plan not under BME management**	**Treated Risk Rating**	Moderate (8))** depends on device		
Description: *Event-cause-consequence*	Unsafe biomedical technology due to inadequate replacement may lead to patient harm and patient death	Consequence Level	Major	Likelihood Level	Unlikely
Context: *Describe the scope and context of the risk*	**Biomedical technology can become hazardous with age and require replacement.** SA BME provides a system of controls to provide a replacement plan for biomedical technology. Adequate levels of protection from safety hazards are expected through its useful life (as defined by the manufacturer) provided appropriate maintenance is performed. The expected life is electronic 7 years, mechanical 10 years (Independent Hospital Pricing Authority).	**Primary Consequence Type**	Clinical		

Causes *Key factors contributing to the risk occurring*	**Consequences** *Primary impacts should the risk occur*	**Controls** *Key activities performed now that reduce the risk*	**Treatments** *Key future actions planned to further reduce the risk*
Existing fleet: • Not in LHN replacement plan • Not meeting current safety requirements (or unknown) • Records of registration, maintenance, hazards and incidents not kept and analysed to identify aged, dangerous or obsolete fleet Insufficient operating or capital funds allocated	Patient harm due to: • Sub-standard design • Obsolete or aged equipment that is hard to maintain	(Move to treatment if they do not cover all biomedical technology) • Asset Management: Property, Plant and Equipment Lifecycle Policy Directive • Asset Management: Biomedical Technology Guidelines	Develop LHN plan with resources to: • Register all biomedical technology • Validate condition & compliance • Develop replacement plan with priority for non-compliance • BME oversight of actions for hazards, recalls, and incidents

APPROVED BY: Anne-Louise Smith, Director SA BME and Asset Management **DATE: 7/5/2021**

Appendix 6: BME Assurance with Resource Estimate

Assurance of biomedical technology management ensures consistent and cost-effective management[1] whether support is in-house or by external suppliers, regardless of the ownership.

Assurance by BME may require additional resourcing which can be estimated once the level of assurance is determined.

1. Select appropriate level of management assurance (Table 18) taking into consideration:
    - Service contract:
        i. If the service provider is not appropriate, then BME should manage the contract and change the service provider.
        ii. If the service provider is appropriate but there is no effective contract manager within LHN or SA Health, then BME should manage the contract.
        iii. If the service provider is appropriate, AND there is an effective contract manager, then BME can provide an advisory role to the LHN/SAH contract manager.
    - Inherent risk rating of biomedical technology:
        - High 16 (or above): recommended BME provide full management.
        - Moderate 9 and not under appropriate contract with LHN management, then BME should provide full management.
        - Low (1) and the SA BME Maintenance Plan Assessment confirms no scheduled maintenance required, then it may be acceptable for BME to register a single generic asset that identifies the service provider and contract details.
    - Maintenance plan - if required (legislation, regulation, calibration compliance, or manufacturer recommendation supported by BME historical records), BME record this in BAMS with unique asset registration.
2. Determine time for core services: Table 19 BME Assurance of core services requiring time
3. Estimate resource: Table 20 Resource effort estimate for BME assurance

Table 18 Levels of BME Assurance

Name	Description	BME responsibility	Remaining risk
None	No BME knowledge, OR Adhoc awareness, individual or BME Manager may be aware of existence Eg. SAAS, DASSA, Mental Health	None No process for recording, monitoring or sharing knowledge.	All risk with Clinical Dept & LHN

[1] **Lessons learned** - Recent examples where increased costs and risks to LHN for inappropriate contracts:
- Alternating air pressure mattresses (rented) – were being repaired in-house at cost, as BME did not know devices were under rental/lease agreement.
- Anaesthetic vaporisers (volume contract) - LHN charged for overseas service included in contract cost.
- Enteral nutrition pumps (consumable contract) - hazards not acted on, scheduled maintenance not performed over 7-year period even though included in contract that BME were unaware of.
- Beds (old AGFMA) – no service records, age unknown, last scheduled maintenance unknown, make and model unknown, hazard and recalls unable to be actioned or recorded as completed.
- Operating pendants and lights (old AGFMA) - not inspected and structurally unsound, expensive repair.

Name	Description	BME responsibility	Remaining risk
Contract advisory	LHN have an effective Contract Manager with BME providing technical expert advice. Eg. Devices serviced by SA Gov (AGFMA) or LHN agreement (PPP) or under rental or lease agreements (e.g. hire of alternating air mattress)	Review reports provided to contract manager to assure AS3551. Register assets if SA Health own (or will own): monitor hazards, alerts and incidents; plan replacement. If SA Health will not own assets, register a single generic asset to ensure BME know service provider (and don't repair in-house).	LHN Contract Manager may not seek advice. Annual monitoring may be insufficient to identify that contractor has failed to manage to AS3551[2] No lifetime record of maintenance history, or scheduled maintenance. Unregistered: LHN don't know how many, model, serial #, expected life; no hazard, recall, or incident actions; no replacement plan
Full service	BME provides all services with either in-house support, or by managing a contract and providing services not in contract. Eg. Most biomedical technology	Framework of system controls in place and managed to AS3551 Lifetime record of service history linked to assets.	Minimal risk with continual monitoring and review by system controls

Table 19 BME Assurance of core services requiring time

Item*1	Core services	Contract advisory 1day/yr + 1dy/meeting C1	Add asset register 15min /asset C2	Full support 2-15% asset value F1	Full support with contract 1% contract value F2
1.1	Replacement planning and coordination	Yes	Yes	Yes	Yes
1.2	Acquisition: purchase, procurement, lease or rental, loan or trial, donation	Yes		Yes	Yes
1.3	Asset registration and auditing, ensure standardisation, monitoring and review	Yes	Yes	Yes	Yes
1.6	Maintenance plan and scheduling		Yes	Yes	Check and add to BAMS
2.2	Breakdown repair	Maybe		Yes	Yes if not in contract
2.3	On-call	Maybe		Yes	Yes if not in contract
2.4	Scheduled maintenance	Maybe		Yes	Check and store service reports

2.6	Incident investigation	Yes	Yes	Yes	Yes
2.7	Hazard and recall alert actions	Yes	Yes	Yes	Yes
2.9	Contract management	Yes		Yes	Yes and procure
2.10	Management of external contractors	Partial		Yes	Yes
3.0	Disposal, sale, trade-in or reallocation	Yes		Yes	Yes

*[1] Item numbers from Asset Management Biomedical Technology Lifecycle Guidelines

Table 20 Resource effort estimate for BME assurance

Code	Level	BME Role	Estimated technical time (additional FTE) [1,2]
A	None	Awareness maybe	
C1	Contract advisory -includes rental or lease	BME review of service provider reports for LHN contract manager to confirm management is to AS3551: • Asset list & age (register, replacement plans) • Breakdown repairs (service history) • Scheduled maintenance plan (checklist), schedule, status complete & overdue • Hazard, recall & incident actions • Technical staff with CV/training	Immaterial if few small contracts for BME technical advice, basic $600 to $3,600 /year per contract 1 day to read T&C and register + 1 day per contract meeting Up to 5 days per year if quarterly reports to be checked
C2	Contract advisory - with register	Options: a) Register generic asset for rental or lease OR register assets if SA Health own or will own), either b) Use service provider details (install dates, condition), OR c) BME inspect assets, validate condition and compliance Hazard, recall and incident actions; replacement plans	Register: a) Generic: 1/2 hr per asset group in agreement b) Minimal (data cleansing, upload) if asset doesn't need inspection, OR c) Estimate 15 min/asset (not including travel time) Ensure data standardisation, monitoring and review.
F1	Full - in-house	BME register all assets Plan maintenance Hazards recalls and incidents actioned Replacement planned Perform work in-house recording all service (breakdown or scheduled).	Estimate at 2-15% asset value (COSR[3]) or use actual cost if known (plus FTE) Register 15min/asset + 1-4 hr develop maintenance plan and schedule + 0.62 hrs/asset/year[4] +parts
F2	Full - contract manage ment	Procure and manage contract/ors Collect and load all service reports (PM and breakdown) Review contract annually with service provider Provide services not in contract	Estimate at 1% contract value +1-5 days procurement/yr +1 day/year contract mgmt +1 day/contract service review +15min/asset to upload service report x frequency + additional work not in contract +breakdown repairs & parts

Abbreviations: A, aware; C1&C2, Contract with limited service; F1&F2, Full service.
Notes:
[1] Technical time average rate updated by SA BME each year, $88/hr in 2020, includes management and admin time associated with all work.
[2] BME can provide historical data if similar asset types exist in database for SA Health.
[3] CoSR see Table 23 Benchmark cost of contract (CoCR) and service (CoSR) ratios.
[4] SAH2020-21 Core Activity report: For 110,000 assets each year the two main tasks (65% work) are Corrective Maintenance 37,481 hrs and Scheduled Maintenance 30,636 hrs, totalling 0.62 hrs/asset/per annum. This is 6200hrs for 10,000 assets, or 4.6 FTE (at 1350 chargeable hours per technical FTE).

Appendix 7: Contract Advisory Service Detail

BME LHN can provide technology-specific advice to the LHN (or SA Health) Contract Manager regarding maintenance (preventive and breakdown) provided and should confirm what BME services are outside the agreement.

Table 21 Technology-specific details for BME assurance of Contract Management

Governance of Contract	Technical advice for LHN Contract Manager
1. How do all stakeholders know who is doing what? i.e. Is device (or generic) registered on BAMS with service provider identified 2. Who is contract manager for LHN (or SA Health)? 3. Where is contract kept? 4. What are the Terms and Conditions of the contract? i.e. Coverage – is it comprehensive, does it include parts, how often and what scheduled maintenance is performed? Response times – Business hours only? Additional cost for out of business calls? 5. What are the technical KPI that are being reported on and how regularly? 6. How often are service provider meetings held and who attends? 7. Who is responsible for managing replacement planning (capital or operating)?	1. What devices are being serviced i. View list of assets with make-model, serial number and installation date ii. Is condition reporting included? iii. Ae SA Health owned assets in BAMS? 2. Maintenance planning process iv. Schedule and checklist appropriate v. According to manufacturer recommendation vi. If not appropriate documentation to support change 3. Assess scheduled PM reports for period vii. What assets are included? viii. Have PM been performed? ix. What failures occurred and what actions have been taken to correct? x. How many were not achieved? 4. Assess breakdown repair report for period xi. What assets are over-represented (multiple breakdown repairs) xii. Appropriate time, tasks and costs (check outliers) 5. Hazards, recalls and incidents report xiii. Actions taken 6. Has service provider provided assurance that external contractors xiv. Have appropriate technical training xv. Have police checks and immunisations xvi. Are inducted for site 7. Is user training need assessed over contract xvii. By who xviii. Who arranges further user training 8. Is management to AS3551? xix. Ability to provide the above reports is sufficient to assure that biomedical technology is being managed appropriately
Confirm BME responsibility	
1. Replacement program – needs asset registration with condition, installation, expected life 2. Hazards, recalls and incidents – needs asset registration (make & model) 3. Acquisition/disposal 4. Failure (wear & tear) replacement 5. Breakdown maintenance 6. After hours repair 7. Cost of parts	

Appendix 8: Transfer of Biomedical Technology to Management by BME

There is a process for safe transfer of biomedical technology management to LHN BME where they have not previously managed it:

1. Assess risks specific to the LHN and the biomedical technology:
    - Inappropriate maintenance: scheduled PM and/or breakdown repairs.
    - Inappropriate documentation to assure all work done.
    - Core services not previously included (eg, in service contracts).
    - Inappropriate replacement.
2. Estimate additional resources (S&W or R&M budget) beyond LHN BME historical resources, considering:
    - Service contracts only cover limited work, eg, scheduled preventive maintenance, some cover corrective maintenance, and a few include parts. They do not cover the other core services that SA BME should still provide for contracted devices.
    - The LHN Contract Manager may not have the technical expertise to determine if appropriate work is performed or identify risks.
    - Administration fees charged by a service provider.
    - E.g., Historic DIT AGFMA fee 9-12% of work done annually for managing maintenance and contractors, maintaining a database and standard processes (including service provider monitoring) that exclude many core services needed to manage biomedical technology (to AS3551).
    - Compare to known information:
        i. Table 22 Benchmark proportion of BME time for core service.
        ii. Table 23 Benchmark cost of contract (CoCR) and service (CoSR) ratios.
3. Develop business case to transfer management to BME LHN with appropriate resourcing:
    - Cost estimates are interim for at least the first couple of years until confirmation of the condition of the technology and annual maintenance needs (minor and major PM can be many years apart).

Appendix 9: Benchmark BME Time, CoSR and CoCR

- The average time taken to perform in-house BME services can be used to estimate resources when transferring management to BME
    - Cost of Service Ratio (CoSR) includes all services provided by in-house BME and all costs.
    - Cost of Contract Ratio (CoCR) only includes limited services within contract; BME should still provide other services.

Table 22 Benchmark proportion of BME time for core service

Item[1]	Core BME services	BME time[2]	Supplier service[3]	LHN risk
1.1	Coordinating replacement and new initiative program	2%	Not provided	Assets not in replacement program.
1.2	Biomedical technology acquisition: development, purchase/procurement, lease or rental, loan or trial, donation	6%	Not provided	Asset safety over expected life not assured during procurement.
1.3 & 1.5	Asset registration and auditing (stocktake identification of lost assets)	6.8%	0.4%	Assets not identified & not in replacement program.
1.4	Pre-operational testing, commissioning and installation (with documentation) including ICT connections	2%	1%	Safety through life not assured, initial condition and configuration not identified.
1.6	Maintenance plans, review of RTR, analysis of changing risk with age	3%	1%	Safety through life not assured, scheduled maintenance not identified or reviewed.
2.2	Biomedical technology repair (includes provision of loans & spares, and modifications)	40%	10%	Inappropriate breakdown maintenance. Work not documented.
2.3	On-Call service provision	0.2%	0.1%	Functionality not assured after hours
2.4	Biomedical technology scheduled maintenance	30%	87.5%	Inappropriate scheduled maintenance. Work not documented.
2.6 & 2.7	Biomedical technology incident investigation Hazard and recall alerts	1%	Not provided	Assets with recalls, hazards or incidents not identified.
2.9 & 2.10	Contract management & Management of external contractors	8%	Not provided	Technical aspects not managed. Core services not in agreements.
2.11 & 3.0	Asset data update & Disposal, sale, trade-in or reallocation of biomedical technology	1%	Not provided	Track transferred assets. Dispose of safely.

Notes:
[1] Item numbers match BAMS Reports 2021 (from first Biomedical Technology Policy Directive numbering).
[2] BME proportion of time based on 300,000 hrs over 3 years, from SA BME report: SAH Core Activity 2021.
[3] Estimate based on SA Health biomedical technology service agreement provisions.

Cost of Service Ratio, CoSR

- Cost of all BME service divided by the purchase value of all biomedical technology.
- 5% CoSR is the average for all SA BME across all biomedical technology in SA Health.
- This includes all:
    - Asset types (medical, laboratory, dental, imaging).
    - Service contracts.
    - Service not within contract costs (i.e., repairs, parts, overheads, and S&W).
    - BME core services: contract procurement and management; hazards, recalls, and incident actions; service documentation; replacement planning.

Cost of Contract ratio, CoCR

- Cost of contracted services only, divided by purchase value.
    - Usually limited to scheduled maintenance.
    - Sometimes includes comprehensive maintenance (with breakdowns).
    - Rarely includes parts (e.g., glass, detector heads).
- The contract cost excludes services that are still provided by BME:
    - Contract procurement; review; management of external contractors.
    - Breakdown maintenance, parts.
    - Hazard and recall actions; incident investigation; service history validation and document storage; replacement planning.

Table 23 Benchmark cost of contract (CoCR) and service (CoSR) ratios

Service CoSR	Device type	Example
5-6%	CoSR, Cost of service ratio, average statewide BME, for all asset classes. Includes all services not just those in contract.	Averaged across all biomedical technology.
Contract CoCR	Device type	Example
2-3%	Electrical with minimal moving parts. Wear & tear on buttons, switches, openings, mounts and handles.	Most simple technology with no software updates
8%	Mechanical devices	Dental & pathology Alternating air mattress
8-10%	Software support	
10-15%	Complex Operating Theatre equipment Filtration devices with regular filter replacement Sterilising units needing validation Radiographic (not in consolidated contract)	Stereotactic, RF, Phaco, US RO water treatment Sterilisers, washers Medical Imaging
15%-18%	Complex mechanical	Endoscopes