OFFICIAL

SA Health

Policy

Asset Management: Biomedical Technology Maintenance Planning

Version:1.0

Approval date: 03 December 2023

PDS Reference No: D0511

Government of South Australia

SA Health

1. Name of Policy

Asset Management: Biomedical Technology Maintenance Planning

2. Policy statement

This policy provides the mandatory requirements which apply in relation to the maintenance of biomedical technology and test equipment. The maintenance planning process mitigates lifetime risks of biomedical technology and ensures consistency across SA Health sites. The process optimises availability, safety and regulatory compliance of biomedical technologies and ensures controlled risks resulting from their application are within SA Health's acceptable limits.

This Biomedical Technology Policy works with the Asset Management Policy to set requirements for managing risk specific to biomedical technology (such as the Australian Register of Therapeutic Goods (ARTG) - listed medical devices managed by a Biomedical Technology Management Group (BME)) and medical-related devices.

3. Applicability

This policy applies to all employees and contracted staff of SA Health; that is all employees and contracted staff 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).

4. Policy principles

SA Health's approach to biomedical technology maintenance planning is underpinned by the following principles:

> We support that biomedical technology used for health service delivery is appropriate, available, safe, used effectively, functioning correctly, and compliant with relevant laws, regulations, and standards.

> We make operational lifecycle decisions that are based on total cost of ownership, risk, and evidence, supported by asset performance reporting.

> We have accountability of decision-making for lifetime maintenance strategy, planning and implementation that is justified and takes into consideration LHN clinical and business needs.

> We provide transparency to the decision-making process including peer approval of decisions, (not limited to an LHN) using a risk-based approach and supported by documentation.

> We develop lifetime maintenance plans and schedules for all biomedical technology assets used by SA Health.

5. Policy requirements

> All SA Health biomedical technology and its testing equipment must have a maintenance strategy developed during acceptance (or on discovery) to ensure, over its lifetime, it is available, safe, functioning correctly and compliant with relevant laws, regulations, and standards.

Develop a Maintenance Plan

> The maintenance strategy must be documented in a maintenance plan that defines the checklist, frequency, type of maintenance and who provides the service (in-house or external) for the life of the biomedical technology, in accordance with Appendix 1: Asset Management Biomedical Technology Maintenance Planning Policy Mandatory Instruction.

- The default maintenance strategy must follow the manufacturer recommendation for the checklist, frequency, type of maintenance, and service provider.
- A maintenance plan with a different frequency to the manufacturer's recommendation, or with no manufacturer recommendation, must use the risk-based assessment process and include the maintenance plan developed in accordance with Appendix 1: Asset Management Biomedical Technology Maintenance Planning Policy Mandatory Instructions:
    - 1 Risk-based assessment process for developing maintenance plans
    - 2 Criteria for setting frequency
    - 3 Documentation and Record Keeping
    - 4 Authorisation
    - 5 Schedule the Maintenance Plan
    - 6 Review Scheduled Maintenance
    - 7 Review Scheduled Maintenance – documentation and approval
    - 8 Reports for monitoring compliance of Maintenance Plans.

Approve Maintenance Plan

- Maintenance plans must be independently reviewed and approved as detailed in Appendix 1: Asset Management Biomedical Technology Maintenance Planning Policy Mandatory Instructions 4 Authorisation:
    - Input by a range of technical experts to minimise over servicing (increase failure rate) or underservicing (reduce individual workload).
    - Appropriate testing identified in the checklist.
    - Approving technical or site manager must be from a different LHN to the assessor, preferably has expertise with the biomedical technology or equivalent, (usually the approver is from the LHN with the first or second greatest number of the assets under review).
- The approved Maintenance plan (comprising of form, checklist, and associated documents) must be stored in the Biomedical Asset Management System (BAMS). Refer Appendix 1: Asset Management Biomedical Technology Maintenance Planning Policy Mandatory Instruction.

Schedule maintenance

- Each BME technology service group must schedule and document maintenance plans for all biomedical technology assets they are responsible for within their LHN as detailed in Appendix 1: Asset Management Biomedical Technology Maintenance Planning Policy Mandatory Instruction 5 Schedule the Maintenance Plan.
    - Preventative Maintenance (PM) and Performance Verification (PV) must be managed separately to allow independent schedules.
    - Where schedules are developed for medical-related equipment that is not defined biomedical technology, consideration must be given for them being managed in the same way.

Continuous improvement

- Changes to approved maintenance plans must be submitted to the original approver and assessor, where possible to ensure the rationale for the change is supported.
    - If changes are agreed, the original assessor must make the necessary edits to the maintenance plan documents and the original approver must review and sign.
    - Where not agreed, the change request must be submitted to the SA BME Operations Committee for expert advice and decision.

Review Maintenance Plans Atleast Every Three Years

- The state-wide pool of maintenance statistics must be analysed to provide an objective level of confidence that the frequency of PM and/or PV is appropriate for biomedical technology continuing to operate correctly and safely over its life.
- Review scheduled maintenance must occur as detailed in Appendix 1: Asset Management Biomedical Technology Maintenance Planning Policy Mandatory Instruction 6 Review Scheduled Maintenance, and:
    - Be undertaken by a reviewer who is technically competent in the biomedical technology.
    - Review situations where scheduled maintenance could have prevented failure and analyse at least the last 3 years of repair history.
- Reviewer must arrange approval and document the maintenance plan (Refer Appendix 1: Asset Management Biomedical Technology Maintenance Planning Policy Mandatory InstructionAppendix 1: Asset Management Biomedical Technology Maintenance Planning Policy Mandatory Instructions 7 Review Scheduled Maintenance - documentation and approval).
- Additions or changes to maintenance plans are recorded to 'Maintenance Plan Additions and Changes Register' and disseminated via SA BME Operations Committee.
- Senior members of BME must update schedules for their LHN.
    - BME technology service groups must schedule equipment maintenance they are responsible for.

Monitor Compliance

- Reports must quantify where inappropriate maintenance planning may adversely impact patient and staff safety, and equipment availability, over its lifetime using Key Performance Indicators (KPIs), including:
    - Assets with no scheduled maintenance or maintenance not performed to schedule
    - Maintenance plan process incomplete -not created, not approved, not recorded/documented, or not completed, or not actioned by other LHN, and/or
    - Maintenance plan not reviewed at least every three years.
- Reports must be distributed to three levels of the governance framework, for action, with the intent to reduce inappropriate maintenance planning as detailed in Appendix 1: Asset Management Biomedical Technology Maintenance Planning Policy Mandatory Instruction 8 Reports for monitoring compliance of maintenance plans.

6. Mandatory related documents

The following documents must be complied with under this Policy, to the extent that they are relevant:

- Asset Management Policy
- Australian Standard AS/NZS 3551: Management programs for medical equipment

7. Supporting information

- 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 Risk Management Guideline
- SA BME Associated documents (for SA Health internal use only):
    - iApply Maintenance Flow Chart, Application Guide and Technical Guide.
    - BAMS Report: Corrective WO Maintenance Planning Review Tool

- SA BME Assessment – Schedule Audit Tool
- SA BME Biomedical Technology Maintenance Planning Foundation
- SA BME Change Maintenance Plans Report
- SA BME Corrective WO Maintenance Planning Review Tool Guide

8. Definitions

> **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 the departments and people that provide biomedical technology management and maintenance services to SA Health and who 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, 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 of conception, and
- that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means, or
- an accessory to such an instrument, device, equipment, apparatus, or appliance, or
- 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 (such as wireless connection) means is to be considered part of the biomedical technology.

The Manager BME will 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.

> **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.

> **Run-to-Review (RTR)** means assets with no scheduled maintenance requirements (PM or PV) are scheduled for review only. Asset corrective work orders are monitored at least every 3 years to determine if the Maintenance Plan is appropriate and changed if required.

> **SA BME** means South Australia Biomedical Engineering, a state-wide Community of Practice that sets the standard for managing SA Health's biomedical technology and facilitates state-wide 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.

9. Compliance

This policy is binding on those to whom it applies or relates. Implementation at a local level may be subject to audit/assessment. The Domain Custodian must work towards the establishment of systems which demonstrate compliance with this policy, in accordance with the requirements of the Integrated Compliance Policy.

Any instance of non-compliance with this policy must be reported to the Domain Custodian for the Infrastructure and Asset Management Policy Domain and the Domain Custodian for the Risk, Compliance and Audit Policy Domain.

10. Document ownership

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

Title: Asset Management: Biomedical Technology Maintenance Planning Policy

Objective reference number: A5262548

Review date: 03/12/2024

Contact for enquiries: SABMECorporate@sa.gov.au

11. Document history

Version	Date approved	Approved by	Amendment notes
1.0	03/12/2023	Chief Executive, DHW	Conversion of SA BME Procedure to Policy in line with mandating management of medical equipment to AS3551

12. Appendices

1. Asset Management Biomedical Technology Maintenance Planning Policy Mandatory Instruction
2. Inherent Risk Rating for Biomedical Technology Mandatory Instruction

Appendix 1: Asset Management Biomedical Technology Maintenance Planning Policy Mandatory Instructions

The following Instructions must be complied with to meet the requirements of the Asset Management: Biomedical Technology Maintenance Planning Policy.

1. Risk-based assessment process for developing maintenance plans

1.1 The type of maintenance plan must be PM and/or PV or Run to Review.

a) Preventive Maintenance (PM) – reduce probability of failure or degradation of function.

b) Performance Verification (PV) – test essential performance parameters necessary for continued safe use as intended by the manufacturer.

- Expect continued operation until random failure causes a breakdown.
- The PV Checklist is the basis of the pre-use test for acceptance of new assets and must include:
  - Physical (with visual inspection), function and electrical tests
  - Features or interlocks whose function users cannot readily detect during normal operation
  - Calibration essential for correct operation
  - Configuration and software version checks, and
  - Testing of compliance with specific statutory and/or accreditation requirements.

c) Run to Review – no PM or PV required.

- This decision must be in accordance with:
  - Manufacturer recommendation, or
  - SA BME Maintenance Plan outcome.
- Expect continued operation until random failure causes a breakdown.
- Formal review required at least every three years.
- Ensures all devices are a) scheduled for review, and b) included in Review of Scheduled Maintenance to identify early signs of preventable failure.
- Run to Review (RTR) must not be used, even if recommended by manufacturer.

1.2 The manufacturer recommendation for Checklist and Frequency can be used as the default maintenance plan, and must be used where:

a) The inherent risk rating is HIGH (16), and

b) Insufficient service history exists in the BAMS to assure a change to the manufacturer recommendation is appropriate.

1.3 There are other considerations, where expert BME Biomedical knowledge of the reviewer and approver must be used, when there is a deviation in frequency to that recommended by manufacturer in accordance with (AS3551 6.3.1):

a) Australian standards, laws, and regulations.

b) Manufacturer requirements and recommendations.

c) SA Health Risk Management Framework and Risk Appetite.

d) Local operational conditions and operating environment.

e) Type of equipment and its usage.

f) Service history, hazards and recalls.

g) SA BME's ability to influence reliability and in-house expertise.

h) Consultation with end users.

1.4 Changes to the manufacturer's recommended frequency that extends the period between PM or PV must only occur if:

a) The maintenance plan uses the risk-based assessment process defined by this policy.

b) The frequency of service is balanced against the clinical and business risk of the device failing if no scheduled maintenance was performed (Appendix 2 Inherent Risk Rating for Biomedical Technology).

c) There are no known service issues or incidents that require more frequent PM or PV.

d) Formal review of maintenance plan at least every three years.

2. Criteria for setting frequency

2.1 Maintenance plan must be created using:

a) Online Maintenance Planning Smart Form: iApply_Maintenance_Plan.

b) Associated documents include SA BME iApply Maintenance Flow Chart, Application Guide and Technical Guide.

2.2 Prepare information:

a) Existing maintenance plans must be used where one exists and is applicable.

- Confirm operating conditions are the same.

b) Assessment scope: The maintenance plan must apply to an ECRI category, a model, a specific asset in an unusual setting or group of assets in an unusual setting.

- ECRI – provide ECRI code and category description.
- Model - identify manufacturer and model and tick multiple assets across SA BME.
- Asset specific - identify the manufacturer and model and tick specific asset box.
- Group of biomedical technology in an unusual setting – e.g. All in a NATA laboratory requiring common calibration requirements to meet regulations.

c) Identify:

- Special cases and environments: helicopter, NATA
- Inherent risk of biomedical technology - Appendix 2 Inherent Risk Rating for Biomedical Technology Risk 16 or Risk <16.

2.3 High risk (16) - identify mandated PV and/or PM (type and frequency):

a) Regulatory, manufacturing, or environmental.

b) Mandated maintenance (such as ionising radiation compliance testing, NATA requirements)

- State the name of the regulation, date, and section.

c) Manufacturer PM requirements:

- State the name and version of the manual and section(s).
- For an ECRI category, at least two references to manufacturers' recommendations are needed and must reflect the requirements of the whole category.

d) Known high risks: Incidents, hazard alerts, recalls, previous history not addressed by manufacturer PM or PV.

e) Outcome: Maintenance plan uses the shorter interval of Manufacturer or Regulatory requirement.

2.4 Mains powered equipment:

a) Where equipment is not mains powered (battery or manually operated) technical discretion must be used to determine if a run to review (RTR) maintenance plan is suitable for the device. An RTR at this stage of the assessment implies faults are non-critical, obvious to users, and incorrect function is easily recognisable by the user. In this situation no PM or PV is required.

b) Alternatively, if the assessor believes a non-RTR maintenance plan is appropriate, the reasons for this must be documented in the maintenance plan.

2.5 High risk operating environment

a) If the equipment is mains powered and is used in a high risk operating environment, regular testing must follow intervals defined in Safe Work Australia Managing Electrical Risks in the Workplace Code of Practice.

- A hospital clinical setting is not defined as a high-risk operating environment in the Code of Practice.
- High risk operating environments must be stated in the assessment e.g., emergency transport vehicles such as helicopters. The equipment must be assigned an annual PV schedule.
- Where the operating environment is not high risk, other environmental factors must be considered.

2.6 Facility wiring requirements:

a) When equipment is used for patient care in appropriate facilities, with a level of electrical safety inbuilt, a Run to Review maintenance plan may be assigned:

- Medical procedures in a clinical setting are conducted in body or cardiac protected areas, ensuring electrical safety for the patient and user.
- SA BME ensures cardiac protected areas are routinely inspected and tested in accordance with AS3003.
- Laboratories fitted with a 30mA RCD at the distribution board ensures electrical safety for equipment users.
- SA Health equipment users are required to visually inspect the equipment, plug and cord before use.
- Note: Some healthcare facilities, or sections of (typically older or repurposed facilities) may have no cardiac or body protection. Where there are sections without this inbuilt protection, consideration of equipment moving into those sections from compliant areas needs to be considered.

2.7 Equipment used in the home and AS3003 wiring requirements:

a) The home is a normal place of residence that is not an institution providing care on a commercial basis. Refer AS3003 Electrical Installations – Patient Areas Section 1.5.13 Homecare.

b) When SA Health owned equipment is used in the home, the house wiring must comply with the legislative requirements of AS3003 Patient Wiring: Section 5.2 Homecare Installations.

- An internally powered or Class 2 device provided with Type BF or Type CF applied parts can only be used in a house wired in accordance with AS3000.
- A Class 1 device or provided with a Class B applied part can only be used in a socket outlet fitted with a Type 1 RCD. The RCD must be tested annually, and test documents retained. Refer AS3760:2010 In-service Inspection and Testing of Electrical Equipment. Section 2 Inspection and Tests Clause.

c) Where the home complies with AS3003 the equipment must be assigned a maximum of 5 yearly PV plan for Class 1 devices as SA BME considers the home environment to be harsher than a clinical setting:

  - Users of equipment are not professionally trained
  - No formal requirement for visual inspection of damage to equipment, leads and plug, and
  - Technical support and repair service is not readily available.

d) Where the home does not comply, the equipment must not be used until the home becomes compliant. Typical situations for non-compliance are:

- The equipment is Class 1 or is supplied with a Type B applied part and used in a home that is not compliant with AS3003 Section 5.2 Clause 5.2.2.
    - The equipment must be replaced with a Class 2 equivalent (where possible) and home checked for compliance with AS3000. If a Class 2 equivalent is not available, SA BME must inform the clinical prescriber of the legal requirement to have the home meet AS3000/AS3003 before equipment use. Where the clinical need is urgent the equipment can be supplied with an inline RCD, as a temporary measure (up to a max of 90 days) allowing time to comply.
- The equipment is Class 2 but the home is not wired in accordance with AS3000.
    - The users must be informed of their legal requirement to ensure their home meets AS3000 Electrical Installations (Wiring Rules) and Amendments. Once compliant the equipment can be used in the home and assigned a 5-year PV plan if not designed for home use with no maintenance.

2.8 Movable or Class 1 equipment:

a) When patient care equipment is used in a setting without cardiac or body protection, or when equipment (not used for patient care) e.g. a laboratory equipment is used in a facility without 30mA RCD protection; a layer of electrical safety provide by the wiring in the facility is absent. In this situation the electrical safety risk is higher for equipment that is:

- Mobile, as damage to the power cord and device is more likely than for fixed equipment and
- Class 1 - no inbuilt electrical safety layer that double insulated (Class 2) device provides.

b) In either case a two-year PV maintenance plan must be assigned.

c) Where the equipment is not mobile or not Class 1 a Run to Review maintenance plan must be assigned.

2.9 Checklist content and support intervals:

a) Where the equipment maintenance is not high risk (16) professional judgement must be used to determine the maintenance plan interval provided a risk assessment has been done and the approved maintenance plan is reviewed every three years.

b) The risk level of the equipment is based on considerations of equipment function, potential for serious injury, dangerous energy, incident and maintenance history, clinical requirements, end user input and special considerations, SA Health Risk Management Framework.

- 16 High Risk: failure will have major consequences.
- 9 Moderate Risk: failure will have medium consequences.
- 4 Low Risk: failure will have minor consequences.
- 1 Low risk failure will have insignificant consequences.

c) If the determined risk level differs from the risk code in the BAMS, discuss with your manager to determine if it must be changed or if a more appropriate ECRI category must be chosen. Consideration to change the code must be communicated to the Operations Committee who will make a final determination.

d) Where the current risk level in the BAMS is 16, the maintenance plan usually follows manufacturer maintenance recommendations unless BME has knowledge to indicate this can be modified. Otherwise, the maintenance plan can consider changes to these recommendations.

3. Documentation and Record Keeping

3.1 The Maintenance Planning Form must record the assessor, assessment process, final maintenance plan, risk considerations and approval.

a) The assessor must be an appropriate member of BME that is responsible for that type of biomedical technology.

b) It is usually allocated to the BME with the highest number of the asset type.

3.2 Maintenance Plan Summary and Checklist Content:

a) iApply Smart Form summarises the maintenance plan, with both the manufacturer recommendation and SA BME maintenance plan. The reason for the SA BME maintenance plan decision must be on the comments field.

b) Must identify and name an existing checklist to be used for the PM and PV as appropriate, otherwise create a new checklist.

c) The checklist must:

- Address latent risks identified (where applicable).

d) All new checklists must be retained for version control. A screen capture of the checklist is acceptable. The new checklist must be saved with the Biomedical Technology Maintenance Planning Form using naming convention:

- ECRI assessments: ECRI No_ECRI Name_YYYYMMDD _ FirstLetterOf NameSurname of assessor.
- Model or Asset assessments: ECRI No_Manufacturer_Model_YYYYMMDD _ FirstLetterOf NameSurname of assessor.

e) Identify checklist content that varies from the manufacturer's recommendations in Form, Table 2.

3.3 The Maintenance Plan Form, checklist and associated documents must be stored:

a) In the BAMS (if enabled, or in SA BME Shared folder until enabled).

b) With approval date in the file name, as per SA BME BAMS User Guide and Business Rules.

c) For model and asset specific assessments, the Maintenance Planning Form is also documented against the model or asset in the BAMS.

d) PM and PV may have separate checklists.

3.4 The assessor must complete the documentation and store documents:

a) Complete the Assessed by fields on the Maintenance Planning Form and identify the approver in the Approved By name field.

b) Save the Biomedical Technology Maintenance Form, checklist, and associated documents in: N:\Information (C)\SA BME Risk Assessment-Checklists Docs\Completed Assessments, Not signed.

c) Create a folder in this location if needed named: ECRINo_ECRIName

d) Save Biomedical Technology Maintenance Planning Form as named from iApply.

4. Authorisation

4.1 A Maintenance plan must be approved before being actioned.

4.2 The assessor identifies an approver who must:

a) Be an appropriate senior member of BME.

b) Have the largest or second largest number of assets (or equivalent type of technology) under review.

c) Not be at the same SA BME site as the person performing the assessment.

4.3 The approver must review the assessment and authorise.

4.4 An approver must:

a) Only approve if they are appropriate approver.

- If not, they are required to inform the assessor and cease involvement.

b) If appropriate, review the completed form, checklist and associated evidence provided by the assessor.

c) Ensure the process has followed this policy and request correction as required (e.g., storage of files, current version documentation is used, completion of all sections, suitable evidence).

d) Request further information if required.

e) Complete their review in a timely manner.

f) Approve the maintenance plan and checklist by approving it in iApply.

5. Schedule the Maintenance Plan

5.1 Completed Maintenance Plans can be identified in the SA BME Assessment – Schedule Audit Tool that identifies equipment within each LHN that has been assessed and not scheduled.

a) Assessor must schedule the assets within their technical department.

b) Senior members of BME, eg Technical and Site Managers must regularly review the Schedule Audit Tool.

c) BME technology service groups must schedule equipment they are responsible for.

5.2 Once the maintenance planning assessment has been approved the assessor must, as detailed in the SA BME BAMS User Guide and Business Rules:

a) Schedule the equipment for PM and/or PV (within their Technical Department ONLY) in the BAMS.

b) Schedule a review of the Maintenance Plan at least every three years (Schedule type Maintenance review, PM type Recurrent Tasks) where the maintenance plan:

- Differs from the manufacturer's recommendation.
- Follows the manufacturer's recommendation of RTR.

c) Ensure the checklist is in BAMS.

d) Assign the appropriate technical fields to the assets you are scheduling only. Both the manufacturer's requirement and SA BME approved maintenance plan must be shown with the associated interval where required.

MANUFACTURER'S RECOMMENDATION: PM
MANUFACTURER'S RECOMMENDATION: PM
MANUFACTURER'S RECOMMENDATION: PV
MANUFACTURER'S RECOMMENDATION: PV
MANUFACTURER'S RECOMMENDATION: PV + PM
MANUFACTURER'S RECOMMENDATION: RTF

AND

SA BME: ASSET SPECIFIC PM
SA BME: ASSET SPECIFIC PM + PV
SA BME: ASSET SPECIFIC PV
SA BME: ASSET SPECIFIC RTF
SA BME: PERFORMANCE VERIFICATION (PV)
SA BME: PREVENTATIVE MAINTENANCE (PM)
SA BME: PREVENTATIVE MAINTENANCE (PM)
SA BME: PV + PM
SA BME: RUN TO FAILURE (RTF)

e) Store the approved Biomedical Technology Maintenance Planning Form, checklist and associated documents in: the appropriate folder *outside of AssetPlus.*

f) In addition, assessments must be in AssetPlus as a document type maintenance plan:

- Model specific: against the model.
- Asset specific: against the asset.

5.3 The assessor deletes associated forms in the N:\Information (C)\SA BME Risk Assessment-Checklists Docs\Completed Assessments, Not signed.

6. Review Scheduled Maintenance

6.1 Maintenance Plans (forms, checklists and schedules) must be reviewed at least every three years if:

a) Frequency is different to the manufacturer's recommendations.

b) No PM is recommended by the manufacturer, or by SA BME (Run to Review).

c) Low levels of failure make it difficult to detect preventable failures.

6.2 Maintenance plans must also be reviewed as required when it is identified that:

a) PM and/or PV could prevent or minimise breakdown.

b) Hazard, recall, safety issue or incident (SLS) indicate further failure could be prevented.

6.3 Allocate reviewer:

a) Senior members of BME, eg Technical and Site Managers must identify Maintenance Plans due for review in the BAMS.

b) The reviewer is usually the BME that did the original assessment, but any site can review as needed.

6.4 The reviewer must review situations where scheduled maintenance could have prevented failure.

a) Use the BAMS Report: Corrective WO Maintenance Planning Review Tool to flag repairs that may be avoidable by a change in checklist or frequency:

- Insufficient/ lack of PM flag
  At least one corrective work order within the last three years with a cause: Insufficient/Lack of PM.

- Corrective work orders per asset flag
  Set when the failure rate has increased over time and rapidly.

  - More than 20 WO in the last year.
  - >70% increase compared to previous years, or
  - Average WO/asset/year >1 for last three years and risk 9 or 16.

- Mean time between failure flag
  Increase in the meantime between PM preventable failures

  - Inverse average failure rate: (sum of device ages)/(number of failures due to lack of PM).
  - Thresholds based on biomedical technology inherent risk (if no maintenance performed): Risk 16 MTBF <75; Risk 9 MBTF <50; Risk 4 MBTF < 25.

b) Hazard, recall, safety issue or incident (SLS): review failures that could have caused major consequences and are preventable by changing the maintenance plan.

6.5 If there are any flags noted, the reviewer must analyse at least the last 3 years of repair history:

a) Discuss with technical staff that completed the repair work to determine if a change to the maintenance plan is likely to reduce failure and/or increase safety.

b) Change maintenance plan checklist or frequency as needed.

7. Review Scheduled Maintenance - documentation and approval

7.1 The reviewer must document the process:

a) Document the maintenance plan and associated assets with specific text used in BAMS

b) Update the Maintenance Plan Additions and Changes Register.

7.2 If there is no change to a maintenance plan, the reviewer must:

a) Generate a quick work order linked to associated assets (see Quick WO instructions in SA BME BAMS User Guide and Business Rules).

b) Enter the Request Detail field with "Repair history and previous maintenance plan reviewed", and either:

- "No flags set, no change to maintenance plan", or
- "Flags set and investigated, no change to maintenance plan."

7.3 After a change to a maintenance plan, the reviewer must:

a) Complete the new Maintenance Plan form with the recent repair history indicating the needed change.

b) Seek approval of change with the same process as newly created maintenance plans.

c) Generate a quick work order (see Quick WO instructions in SA BME BAMS User Guide and Business Rules).

- Enter text to Request Detail field: "Repair history and previous Maintenance Plan reviewed", and add one of:
  - "Flags set and investigated, asset history indicated a change to maintenance plan. Maintenance planning form updated and approved. See Maintenance Planning Form for further details"
  - "Change to response to Maintenance Planning Form questions. Updated Maintenance Planning Form approved. See Maintenance Planning Form for further details" , or
  - "Flags set and investigated, asset history indicated a change to maintenance plan required AND change to response to Maintenance Planning Form questions. Maintenance Planning Form updated and approved. See Maintenance Planning Form for further details."
- Set quick WO Corrective Action to MAINTENANCE PLAN CHANGE.
  This will allow it to be in the SA BME Changed Maintenance Plans Report.

8. Reports for monitoring compliance of maintenance plans

8.1 Reports must be distributed to 3 levels of the governance framework, (Oversight, Leadership and Operations), for action to reduce inappropriate maintenance planning.

a) Operational actions to be monitored by senior members of BME, eg Area, Site and Technical Managers - monthly LHN reports.

b) Strategic actions to be monitored by SA BME Leadership Committee - monthly SA Health summary report.

c) Governance and risk mitigation to be monitored by SA BME Oversight Committee - quarterly SA Health summary.

Table 1 Reports and actions for monitoring compliance of maintenance planning

Reports	Action by Technical Managers	SA BME Leadership & Oversight
1. Acceptance assets report: New assets not scheduled for maintenance	Technical Managers supervise technical staff not completing maintenance plans or scheduling during acceptance	Number of new assets with no maintenance plan
2. Assets without PM: either not on PM schedule, or PM overdue	Technical Managers allocate tasks: a) assets all on schedule b) assets tested as per schedule	%Assets not under PM (KPI3) Assets overdue for PM (KPI3b)

Reports	Action by Technical Managers	SA BME Leadership & Oversight
3. Maintenance Plan reviews due	Technical Managers allocate reviews to technical experts	Number of Maintenance Plan reviews overdue

Appendix 2: Inherent Risk Rating for Biomedical Technology Mandatory Instruction

Risk means the inherent risk of the device as delivered without consideration of further controls or treatments that are in place or may be put in place (scheduled maintenance).

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.

Source: extract from SA BME BAMS User Guide and Business Rules, March 2021, Section 14.4 Risk