

4 International Clinical Engineering & Health Technology Management Congress

October 24-26, 2021 - Virtual Edition

A Risk Based Approach to Biomedical Device Maintenance

Adrian Richards

Biomedical Engineering Manager

Women's and Children's Health Network

Adelaide, South Australia

Glenn Kennett

Operations Manager

SA Biomedical Engineering

Event Website: <https://www.globalcea.org/icehtmc>



The Healthcare and CE Setting

- The majority of acute healthcare, and all tertiary referral services, in Australia are provided by the government in “public” hospitals
- Clinical Engineering (CE) staff are employed by these hospitals to manage the technology
- In the state of South Australia (population 1.8m, 4,500 public hospital beds) for a short time CE services in all public hospitals were centrally managed – single database for 120,000 devices
- This presented the opportunity to substantially revise our approach to schedule maintenance
- CE activities defined by a voluntary but universally applied standard - AS/NZS 3551
Management Programs for Medical Equipment

Objective

- The development of a risk and evidence based system to define the management approach for scheduled support of BME devices
- Move on from more traditional approaches – optimise resource utilisation and embrace “run to failure” concept
- Remain fully compliant with Australian Standards which states:
 - Follow the manufacturers recommendations
 - or
 - Document the rationale for variation from this
- Close the loop by reviewing outcomes and evidence every 3 years

Key Decision Points

- Legislated requirements – very few
- Manufacturer's recommendations – parts durability e.g. 1000 hour kit
- Latent risk – clinical, financial, legal, reputational
- Power source
- Environment – e.g. hospital vs home use
- Protection incorporated into facility power wiring - AS/NZS 3003 *Patient Area Electrical*

Installations


The Decision Process

SA BME Biomedical Technology Maintenance Planning Flow Chart



The Decision Process

- Uses an on-line “smart” form that guides staff through the decision flow chart
- It is completed by a senior staff member at a site that has the most examples of the device being assessed
- The assessment is reviewed and signed off by a senior staff member at another site


Government of South Australia
 SA Health
 SA Biomedical Engineering
"We care for the technology that cares for you"

Maintenance Planning Form

Creator Details	
Name	Scott McGarry
Email Address	scott.mcgarry@sa.gov.au
Created	01/10/2021 12:52:42 PM
Application ID	10141266

Level of Assessment - Model	
<i>*This is a new maintenance plan and not replacing an existing plan.</i>	
ECRI Number	15109
ECRI Description	BILIRUBINOMETERS
Risk Category	4
Model	MU20105
Manufacture	draeger

Assessment	
Is this assessment a special case? (e.g. Homecare, Helicopter, etc)	No
Does the manufacturer require or recommend PM?	No
Select one or more of the following that apply: (Leave unchecked if none)	The device is non-mains powered or battery operated

Maintenance Plan	Manufacturer's Interval	SA BME Interval
Preventative Maintenance (PM)	None	Run to review
Performance Verification (PV)	None	Run to review

Justification for Decision / Comments:

Device has a self calibration that is user operated

Approval	
Approver Name	Daniel Fletcher
Name	Daniel Fletcher
Email	daniel.fletcher@sa.gov.au
Comments	Approved
Approval decision	The application is APPROVED
Date	05/10/2021

For official use only I3 - A2

Regular Review

- At 3 yearly intervals to “close the loop” and use any evidence arising to further modify the approach
- Looks at the following via automated reports:
 - “Insufficient PM” flag that is captured during repair work
 - Number of corrective work orders
 - Mean time between failures

Effort and Outcomes

- Total time investment - equivalent of 1 person for 12 months
- Substantial student project time – up to 57 weeks
- 347 assessments undertaken at the device category level
- 59 make/model specific assessments undertaken on high inherent risk devices
- Approx. 40% of devices now not scheduled for testing – run to failure
- Now embedded in practice and widely accepted by clinicians and healthcare executives

Adrian Richards

Adrian.Richards@sa.gov.au

*Women's and Childrens Health Network
Adelaide, Australia*