Introduction

Medical devices include instruments, medical equipment, implants, disposables, and software, used mainly for the purpose of diagnosis, monitoring or treatment of diseases, even replacing physiological functions. New medical devices are developed continuously, so through assessment of needs, verification of safety and efficacy, rational procurement, proper installation, preventive maintenance, rational use and quality assurance, a better use of resources is accomplished.

Biomedical engineers and related professionals play an important role in the proper design, development, selection, management, maintenance and user training of medical devices. Effective engineering management prevents a disproportionate rise in the maintenance costs, and improves the quality and safety of health-care delivery. The selection and use of medical devices has to meet priority needs, be in accordance with the existing infrastructure and services and have a budget for operation and maintenance, in order to prevent misdiagnosis or delays in treatment due to lack of available medical equipment.

Maintenance of Active Medical Device

A Medical Device is defined as any instrument, apparatus, appliance, material or other article whether used alone or in combination, intended by the manufacturer to be used for human beings for the purpose of control of conception, diagnosis, prevention, monitoring, 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 physiological process. Surgical instruments are medical devices. Medical Devices play an important role in supporting patient care.

This Malaysian Standard applies only to all active medical equipment placed for use in any healthcare facility which requires maintenance. It is also intended to help them set up systems that will minimise risks associated with the use of those medical devices. "Active medical device" means any medical device (medical equipment) relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.

According to WHO, it is estimated that around 50% of medical equipment in developing countries is not functioning, not used correctly, and invariably not maintained, with serious consequences for patient care. This may be because the equipment was not needed or not appropriate, and most often lies idle for want of a spare part. It is critical that a medical device management policy exists that includes a financial provision for maintenance, spare parts and training in the initial cost of the equipment.

Scope

This Malaysian Standard applies to all active medical equipment placed for use in any healthcare facility or any other facility which requires maintenance. This standard is not

applicable for medical equipment placed and used in any facility not intended to be used on human.

This Malaysian Standard provides guidance to all Biomedical Engineering Maintenance Services on:

Responsibilities

Biomedical Engineering services (Section 5); implement and manage the organisation's equipment maintenance program; obtain required facilities and equipment for the organisation's maintenance program; ensure equipment is maintained in a serviceable condition at all times; plan for equipment support in the conceptual phase of each new equipment system; develop an equipment management plan; develop and publish local policies and operating instructions (OI) as required; develop references from the maintenance management report to evaluate the effectiveness of the maintenance programs; establish a work control and priority system to ensure uninterrupted service to supported activities; establish a periodic maintenance and inspection schedule and ensures maintenance personnel perform scheduled maintenance; manage the appropriate use and supply of spare parts; outsource maintenance service of those systems when there are no adequate training, tools, test equipment, and staff.

Biomedical Engineer/technician (Section 5); comply with competency requirements; register with the Board of Engineers as per specified in the Registration Of Engineers Act; attend relevant trainings and/or continuing professional development (CPD) trainings with recognised and authorised professional bodies; manage and administer Biomedical Engineering Services.

Medical device user related to maintenance (Section 5); equipment is used only for its intended purpose, operate equipment in accordance with user's manuals and appropriate user maintenance is performed. Home users shall ensure that only competent individual/organisation carry out maintenance on their equipment.

Maintenance

Schedule maintenance included planned preventive maintenance PPM, calibration, user maintenance (Section 6); Biomedical Engineering Services shall ensure an optimum performance, safe operation, minimum downtime, and maximum useful life from each equipment system. The scheduled maintenance program consists of a series of planned maintenance requirements and inspections. The program is designed to ensure that medical equipment is maintained in the highest possible state of operational throughout its life cycle.

Unscheduled maintenance (Section 7); Unscheduled maintenance involves those actions necessary to restore normal function, safety, performance, and reliability to malfunctioning equipment.

Acceptance tests for newly delivered devices (Section 8); Acceptance testing shall be carried out for all newly introduced equipment before it is placed into clinical service and shall include visual inspection, electrical safety test and performance test.

Management

Mechanisms to avoid failure or breakdown during use (Section 9); Biomedical Engineering Services shall provide mechanisms to avoid failure or breakdown of equipment during patient treatment, diagnosis and therapy. Shall review health alerts, equipment failures, incidence reports, use errors, component failures and carry out corrective action.

Uptime (Section 10); Biomedical Engineering Services shall identify applicable uptime and achieving uptime target for all equipments in service. Calculation method on uptime.

Quality assurance program (QAP) (Section 11) for continuous improvement; Biomedical Engineering Services shall provide healthcare facility authority the agreed information and maintain accurate records, procedures and other documents in the QAP. The data collected shall be analysed for further improvement of the structure and processes.

Maintenance management information system - MMIS (Section 12); Maintenance management information system is used to manage all aspects of the Biomedical Engineering maintenance services. The MMIS should consist, but not limited to, the following modules and be accessible to authorised users: asset register module with links to other modules, work order module, planned preventive maintenance module, maintenance history module and supplier-client register module. Healthcare facilities without Biomedical Engineering Services shall maintain a manual maintenance management system.

Management of warranties (Section 13); to ensure that all faults occurring within the warranty period are detected, reported and repaired under warranty provisions where applicable as well as to ensure that all planned preventive maintenance covered under the warranty provision is carried out within the warranty period as per agreed schedule.

Decommissioned equipment (Section 14); The disposal of potentially hazardous equipment, material or components such as batteries, X-ray tubes, vacuum tubes, pressure vessels, radioactive materials and devices that contain toxic materials such as lead, beryllium, mercury or other heavy metals, polychlorinated biphenyls and asbestos, shall be carried out according to established procedures as laid out in relevant national/international standards or national regulations

Processes for handling hazardous/contaminated equipment (Section 15); Decontamination is the process of handling hazardous/contaminated equipment that may involve cleaning, disinfecting and sterilisation and may vary according to the equipment. Failure to decontaminate equipment properly may lead to post-operative infection and the spread of diseases. Failure to maintain equipment decontamination and sustain proper working practices can raise health and safety issues for staff and patients.

Incidents and hazards (Section 16); Procedure shall be followed in order to carry out investigation and corrective actions on incidents and notified hazards. Biomedical

Engineering Services shall manage equipment hazard alerts and recall notices provided by equipment suppliers and/or established organisations. In the event of an incident that involve the same model of equipment in any country or location, the manufacturer or supplier shall inform the healthcare facility authority, user and Biomedical Engineering Services and take corrective action to ensure the equipment is safe to use.

User training (Section 17); Users shall be trained on the proper and correct usage and operation of the equipment. When procuring new equipment, healthcare facility authority shall include a requirement in the contract that the manufacturer or its representative shall provide training for both Biomedical Engineering Services and users.

Stock of genuine spares parts (Section 18); Stock of genuine spares is to guarantee the availability of genuine spare parts from the equipment manufacturer to meet uptime target and availability of equipment for minimal interruption of clinical services.

On site library (Section 19); the library should consist of documents such as: operation and maintenance manuals, electronic schematic/circuit drawings, backup software, relevant standards and regulations, training materials; and other related documents.

Workshop setup (Section 20); Setting-up of an adequately equipped workshop facility for maintenance of medical equipment, safe storage for equipment under maintenance and efficient space utilisation.

Advisory service (Section 21); Advice on the following maintenance provisions shall be obtained from the Biomedical Engineering Services: selection of equipment, equipment installation; discontinuation of use of equipment; replacement of equipment; any adverse events; and condition appraisal of equipment.

Procurement of equipment (Section 22); Healthcare facility authority shall ensure local policies for procurement of medical equipment addresses safety, quality, and performance are observed. Policies should include the need to establish advisory groups to ensure the procurement requirements takes into account the needs of all parties involved in the use, commissioning, decontamination, maintenance and decommissioning of medical equipment.

Biomedical Engineering

Biomedical Engineering is one of several professional disciplines contributing to safe, effective and economical health care. The role and primary responsibility of a biomedical engineering services are management of medical device technologies, including adherence to recognised safety, quality, cost, and efficiency standards.

Biomedical Engineering is a learned profession that combines expertise and responsibilities in engineering, science, technology, and medicine. Since public health and welfare are paramount considerations in each of these areas, Biomedical Engineers shall uphold an appropriate level of competencies embodied in its professional practice,

research, patient care, and training. The level of competencies shall reflect the standards of professional and personal practice for Biomedical Engineers.

Competency levels of Biomedical Engineering Engineer and Technician

The Biomedical Engineering maintenance competency levels are categorised into four technical levels and one management level. To determine the individual competency levels, the guidelines shall be cross referred to the medical device maintenance specialisation classification, competency skills, breakdown maintenance level and management skills level of the Biomedical Engineer or technician. The details of the competency levels are as per the relevant matrix.

Medical device maintenance specialisation classification		Biomedical maintenance competency levels				
		Level 1	Level 2	Level 3[b]	Level 4[c]	Mgmt[d]
		Junior BMET	Senior BMET	Junior specialist	Specialist	
1	**General / Basic** level medical device	**X**	**X**	**X**	**Optional**	**X**
2	**Intermediate** level medical device	**-**	**X**	**X**	**Optional**	**Optional**
3	**High** level medical device	**-**	**-**	**Optional**	**X** [a]	**Optional**

NOTES:

1. Area of specialisation to be declared based on specific model of medical devices.
2. For level 3 competency, the Junior Specialist are be given an option to expand their specialisation level based on their training advancement and experiences.
3. For level 4 competency, the Specialist at vendor and manufacturer are be given an option to exclude the lower specialisation level.
4. For management level, the manager is required to obtain a minimum competency on general/basic level medical device specialisation.
5. The sample of medical device specialisation are given in Tables H2 – H5 and subject to changes based on its complexity and cost of the equipment.

Table above: Competency levels and device specialisation classification matrix

Assessment of Competence and Commitment

The Biomedical Engineer shall have their competence and commitment assessed through a Professional Competency Examination, conducted by the recognized Competency Certifying Body (CCB), authorized by the Ministry of Health. The professional competency review shall include three components; review of experiences documentary evidence, continuous professional development in biomedical engineering and an examination.

Implementation of this Malaysian Standard is currently voluntary, however it is part of Medical Device Act and as we are getting closer to have Medical Device Act regulation

coming into force, the users of medical device and the industry players have to gear up and prepare for change that will affect us all.