Patient Safety-The Role of Biomedical Engineering

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On 12 December 2020 the Healthcare and Biomedical Engineering Working Group under Electrical Engineering Technical Division invited Puan Haslin Ismail, Head, Operation Central Workshop from Edgenta Mediserve Sdn Bhd to deliver a technical talk entitled “Patient Safety-The Role of Biomedical Engineering Services” via online platform. The talk commenced with sharing of some adverse events that had been reported in the media, Top 10 Patient Safety Concerns and Top 10 Health Technology Hazards in 2020 compiled by ECRI as well as the seven serious medical device malfunctions that led to urgent recalls by United States Food and Drug Administration, Department of Health and Human Services.

Patient safety can be addressed through planning, design and installation or design of biomedical equipment and/or periodic maintenance and repair works. Under environment or facilities design the following need to be considered; sufficient movement space, power outlets or sockets, lighting, backup power supply, medical gas supply, addressing special requirements for negative and positive pressure rooms, fire safety requirements in all areas especially operating theaters due to flammable sources, room insulation to avoid radiation leakage, appropriate railing or fencing requirements, signage and avoiding noise pollution. For medical device design ,the following were highlighted: alarm management, device improper assembly or installation, cross contamination, default settings, operator competence, untagged equipment, and manufacturing defects. Finally, for maintenance activities, alarm management, leakage current, surgical fires, cross contamination, untagged equipment and radiation exposure were cited.

The demands for patient safety have risen due to the following factors: increasing aging population, large amount of aging equipment, increased mortality rates, greater reliance on technology for diagnosis and treatment, better informed society, and medical tourism. Several Acts, Regulations and Standards have been developed in Malaysia to address patient safety. Excerpts from the Medical Device Act related to the role of Biomedical Engineering services was shown.

Key points from each clause in the Malaysian Standard MS 2058 Code of Practice for Good Engineering Maintenance Management of Active Medical Devices were highlighted. This standard is applicable to active medical devices placed for use in any healthcare facility or any other facility which requires maintenance but not applicable to any medical device placed and used in any facility not intended to be used on humans.

In the concluding remarks the emphasis was on the need to create a safety culture within the whole healthcare ecosystem. Everyone needs to be vigilant of potential problems. Accidents need to be prevented as much as possible and a blameless reporting mechanism must be established. Patient safety is a collective effort by various individuals in the healthcare ecosystem.