Seminar on Medical Devices

by Ir. Shamila Ariaratnam

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On the pleasant morning of Wednesday, 24 April 2019, the Chin Fung Kee Auditorium at Wisma IEM was bustling with participants as early as 8:30 a.m. Participants included members of the Institution of Engineers Malaysia (IEM), engineers serving the healthcare and biomedical engineering industry as well as other industries, lecturers and of course not forgetting the undergraduates, the future engineers of our times.

The half day Medical Device Seminar organized by the Healthcare and Biomedical Engineering Working Group under the Electrical Engineering Technical Division of the Institution of Engineers Malaysia enlisted eminent speakers comprising of Ir. Sasikala Devi Thangavelu, Director of Policy, Codes and Standards, Medical Device Authority, Ministry of Health Malaysia, Puan Salbiah Binti Yaakop, Senior Principal Assistant Director in the Policy, Codes and Standards Division of Medical Device Authority, Puan Norshafina Binti Sahinin, Assistant Director at Medical Device Authority and Ir. Lim Kim Ten (K.T. Lim), council member of the IEM.

Medical Device Authority (MDA) Malaysia's main objective is to protect the public health and safety. MDA strives to ensure that medical devices in Malaysia are of high quality, effective and safe. In this half a day seminar, the government officials shared with us our role in contributing to the quality of the healthcare system in the country. The session ended with a presentation on the latest updates of IEC 60364-7-710 Ed. 2:2018 Electrical installations of buildings - Part 7-710: Requirements for special installations or locations - Medical locations.

The seminar commenced with Puan Salbiah's topics on the Medical Device Authority Act (Act 738) and Medical Device Act (Act 737). In a nutshell, Act 738 is to provide for the establishment of the Medical Device Authority with powers to control and regulate medical device, its industries and activities and to enforce the medical device laws and for related matters. Act 737 is to regulate medical devices, the industry and to provide for matters thereto. She also touched on Medical Device Regulations which is to provide requirements for registration, licensing and conformity assessment of medical devices.

Puan Salbiah explaining the establishment of the Medical Device Authority

Ir. Sasikala then took over to give an overview of Medical Devices Regulatory Requirements in Healthcare Institutions and the Technical Competency Regulatory Program. She explained the medical devices regulatory framework, responsibilities of establishments, medical devices regulatory program in healthcare institution, requirement on usage, operation, testing, commissioning, maintenance and disposal of medical devices. Under the second topic she enlightened us on the Medical Device Competency Programme for future graduates and for existing practicing engineers the option of online Voluntary Listing of Technical Personnel, Training Body or Competency certification Body under the Medical Device Act using the Medical Device Technical Competency Online System (MEDTCOMP).

Ir. Sasikala engaging with the participants during her talk

Puan Norshafina the third speaker from MDA, succinctly gave us an overview of handling complaints related to medical devices. Complaints received are categorized into either safety and performance related or otherwise. From there a formal process ensues until the matter is resolved. Complaints received by the establishments from users must be treated as a learning curve to improve quality and safety of medical devices.

Puan Norshafina citing an example on medical device complaint

The final speaker Ir. Kim Ten briefly described the requirements for healthcare facilities' electrical installations which started with an introduction on the governing regulatory framework in Malaysia excluding Sarawak. Ir. Kim Ten then moved on to the requirements under IEC 60463-7-710 Edition 2: Low Voltage Electrical Installations -Requirements for Special Installations or Locations-Medical Locations. In summary, he stated that the low voltage installations at healthcare facilities are one of the most complex as compared to other facilities. Therefore, he mentioned that engineers must give equal importance to the safety and quality of electrical installations as well as medical devices. They both complement each other to ensure that the patients receive the best clinical outcomes from the care givers as well as ensuring the safety of everyone using or visiting the healthcare facility.

Ir. Lim Kim Ten having a light moment with the participants