Clinical Engineering in Malaysia – An Update
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Abstract—This paper presents the major structural changes affecting clinical engineering and various factors that have influenced the successful delivery of clinical engineering services in Malaysia. Important events such as the establishment of Medical Device Authority (MDA), the release of Malaysian Standard MS 2058 on Code of Practice in 2008, the pursuit of hospital accreditation as an indication of excellence and the impending implementation of Medical Device Act have all helped to shape the clinical engineering profession in Malaysia.

I. OVERVIEW
On January 1st 1997, the Malaysian government privatized the hospital support services at all government hospitals. The 500 million Malaysian ringgit contract for the yearly expenditure, for 15 years was awarded to three concession companies - Faber Mediserve (M) Sdn Bhd, Radicare(M) Sdn Bhd and Tongkah Medivest (M) Sdn Bhd (now, Pantai Medivest) [1]. The first 15 years of the privatization had seen the introduction of various mechanisms by the government to monitor the effectiveness of the clinical engineering program at government hospitals. Firstly, a ‘deduction formula’ program were implemented in 2001 where certain percentages of the total fee paid to the concessionaires is deducted if they failed to deliver the services as agreed. Secondly, Quality Assurance Program (QAP) was initiated to monitor biomedical equipment uptime which later became one of the major components in measuring the Concessionaire’s performance. Thirdly, the issue of competency of engineers and technicians maintaining biomedical equipment was hotly debated and discussed in many meetings and discussion sessions. The culmination of this ‘competency’ issue was the release of Malaysian Standard MS 2058 on Code of Practice in 2008, in which qualifications, skills and experiences of ‘competent’ engineers and technicians were clearly defined. Furthermore, in 2012, the establishment of Medical Device Authority (MDA) and the release of Medical Device Act (Act 737) for gaze, gave legal impact to clinical engineering where the maintenance and disposal activities are regulated under the Act. The qualification and competency of a person involved in the field of work are also regulated under the same Act [2].

II. MEDICAL DEVICE ACT AND REGULATIONS
In 2011, the Parliament approved the Medical Device Act 2012 (Act 737). The Act has been published in the Gazette in February 2012. The scope of the Act includes premarket, placement on market, postmarket, usage and disposal. The implementation of the Act will start in second quarter 2013 [3]. Currently, the Medical Device Authority is still in the process of finalizing the framework for the control of usage and maintenance. The criteria, conditions and procedures of competency are detailed out in the regulation. The use of standards is also essential in implementing the regulatory framework as it is a tool to show compliance to the regulatory requirements. It provides reference criteria for installation, testing and commissioning and maintenance of medical device to be met. In this case, the MS 2058: Code of Practice For Good Engineering Maintenance of Active Medical Device is to be referred to ensure proper maintenance is carried out.

III. MS 2058: CODE OF PRACTICE FOR GOOD ENGINEERING MAINTENANCE OF ACTIVE MEDICAL DEVICE
The indigenous Malaysia Standard (MS) 2058:2009 “Code of Practice for Good Engineering Maintenance Management of Active Medical Devices” applies to all active medical devices placed for use in any healthcare facility or any other facility which requires maintenance. This standard is only applicable for medical equipment placed and used in a facility intended to be used on human. This standard provides guidance to all the biomedical engineer (BME) and clinical engineer (CE) on their responsibilities with regard to clinical engineering maintenance and management [4].

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REFERENCES

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