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An ISO Guide 25 Certified Testing laboratory for Clinical Engineering Education

[1]Chii-Wann Lin, [2]Po-Quang Chen, [2]Chin-Te Chen, [2]Chung-Ming Lu, [2]Jia-Hung Chien, [2]Chiu-Hung Yang, [2]Chun-Kai, Huang, [1]Chang-Yi Wang, [1]Yung-Zu Tseng, [1]Hwa-Chang Liu

[1]Institute of Biomedical Engineering, College of Medicine and College of Engineering, National Taiwan University
[2]Department of Biomedical Engineering, National Taiwan University Hospital

Abstract

The establishment of a certified ISO Guide 25 testing laboratory for medical devices is an important corner stone for a better national medical device management system and practices of the assorted standards or guidelines. It can also contribute significantly to the educational program for clinical engineer. As a starting point, a medical electrical safety-testing laboratory according to the AAMI ES-1 (1993) and IEC 60601 (1988) has been setup and devoted to the safety of electromedical apparatus with joined efforts of the Institute of Biomedical Engineering, National Taiwan University and Department of Biomedical Engineering, National Taiwan University Hospital. To ensure its quality of services, ISO/IEC Guide 25 is implemented and certified by Chinese National Laboratory Accreditation (CNLA). In view of the global harmonization, this painstaking procedure for a medical device-testing laboratory can be fruitful in the aspects of quality assurance for the imported devices and post-market surveillance. It also has positive impact on the infrastructure of domestic medical device regulation and development. In this report, we will discuss the necessary procedures to train a clinical engineer to account for this need.

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Introduction

In the wake of globalization, the effectiveness of medical devices can be a potential problem for the general health care management system. The initiation of assorted vertical and horizontal standards and guidelines by various groups, such as International Standard Organization (ISO), International Electrotechnical Commission (IEC), American National Standard Institute (ANSI), and Association for the Advancement of Medical Instrumentation (AAMI), etc., can only stress the importance of minimal quality assurance procedures. Even though a lot of these standards set for the scope of medical devices design and development, it is required for the medical device regulation/management system and law enhancement in some disputed cases. This poses a great demand on the educational program of biomedical engineering (BME), especially the clinical engineering (CE). As the existence of tremendous differences between R&D laboratories and CE department in a hospital, the training programs for these two directions should emphasize the common needs, which are the importance of regulations for the graduate students. These important aspects of career path for a BME and/or CE have been put into considerations to design courses in our newly established Graduate Institute of Biomedical Engineering at National Taiwan University [1].

The many faces of quality system can be quite confusing and tedious from the engineering point of views. There are ISO-9000 series, ISO Guide 25, and ISO-14000 for the general concerns of industrial requirements and Good Manufacture Practice (GMP), Good Laboratory Practice (GLP), and Good Clinical Practice (GCP) for the specific concerns of medical device communities ranging from manufactures to the clinical applications. Even though, the essential elements of these quality systems are extremely similar, the practical solutions for each individual system can have different levels of sophistication during the implementation. These detailed implementations have to document in Standard Operating Procedure (SOP) and execute by qualified engineers. This represents both a management and technical challenges for BME and CE.

The establishment of a certified ISO Guide 25 testing laboratory for medical devices is an important corner stone for a better national medical device management system and practices of the assorted standards or guidelines. It can also contribute significantly to the educational program for CE. As a starting point, a medical electrical safety-testing laboratory according to the AAMI ES-1 (1993) and IEC 60601 (1988) has been setup and devoted to the safety of electromedical apparatus with joined efforts of the Institute of Biomedical Engineering, National Taiwan University and Department of Biomedical Engineering, National Taiwan University Hospital [. To ensure its quality of services, ISO/IEC Guide 25 is implemented and certified by Chinese National Laboratory Accreditation (CNLA). In view of the global harmonization, this painstaking procedure for a medical device-testing laboratory can be fruitful in the aspects of quality assurance for the imported devices and post-market surveillance. It also has positive impact on the infrastructure of domestic medical device regulation and development with the supports from government (Department of Health, Executive Yuan) [3]. In this report, we will discuss the necessary procedures to train a clinical engineer to account for these needs.

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Materials and Methods

The training program for a BME/CE to get acquainted with various standards and its practices can be time consuming and exhaustive in all aspects. For the education purpose, the needs to extract and condense the merits of these requirements are obvious. Some topics are identified as follows and should be addressed in the training program.

1. Bio-ethics
2. Background introduction of Standards and Regulations
3. Comparisons of Quality Systems
4. Requirements and Compliance of Quality Medical Devices
5. Regulations

For laboratories engaged in calibration/testing, the details of these topics have two major areas: quality management requirements and technical requirements. The key concept to fulfill quality management requirement is to: plan, do and audit. These requirements should be put in formal documents as quality manual, standard procedure/working instruction, and records for proper management. The technical issues of testing procedures really depend on the types of medical devices. As for an electrical safety-testing laboratory, these include the compliance with environmental requirements (as shown in Table 1) and safety current limits (as shown in Table 2). The testing procedures can be either manual steps or automated via instrumentation control [4]. The use of software should subject to the control of quality documents or product development cycle. The measurement traceability should be installed whenever is possible to ensure the accuracy or validity of services. The uncertainty in measurement should be analyzed and documented for the peer reviews of laboratory capability. The compliance of ISO Guide 25 has to be confirmed by internal and external auditing procedures.

Table 1. Laboratory environmental conditions

Voltage	Frequency	Resistance	Temperature	Humidity	Pressure
104 – 127 V_{rms}	60□1 Hz	<=2□	23□5 □	50□20 %RH	700 – 1060 mbar

Table 2. Safety current limits of IEC 60601 and AAMI ES-1

Classification			Enclosure risk current		Patient-applied risk current (source current)	Patient isolation risk current (sink current)	Earth risk current		
			Cord-connected/ Battery powered	Permanent			General	Other	Permanent
AAMI	Isolated	NC	100	100	10	NA	500	2,500	5,000
		SFC	300	5,000	50	50	1,000	5,000	10,000
	Nonisolated	NC	100	100	10	NA	500	2,500	5,000
		SFC	300	5,000	100	NA	1,000	5,000	10,000
	Likely to contact patient	NC	100	100	NA	NA	500	2,500	5,000
		SFC	300	5,000	NA	NA	1,000	5,000	10,000
	No patient contact	NC	100	100	NA	NA	500	2,500	5,000
		SFC	500	5,000	NA	NA	1,000	5,000	10,000
IEC	CF	NC	100		10		500	2500	5,000
		SFC	500		50		1000	5000	10,000
	BF	NC	100		100		500	2500	5000

		SFC	500	500	1000	5000	10000
	B	NC	100	100	500	2500	5000
		SFC	500	500	1000	5000	10000

Results

After completing all the documentation and necessary training sessions, one can apply for the certification to any ISO Guide 58 certified institutes, which is Chinese National Laboratory Accreditation (CNLA) in Taiwan. The registration items, test items, test methods and range are listed as shown in Table 3. The certificate was awarded on Nov. 1, 1999 after one-year preparations.

Table 3. Applicable testing items, methods, and range of certified testing laboratory

Registration Items	Test Items	Test Methods		Range	Best Test capability Recognized
ED0405 Electromedical for electrical safety	Electromedical apparatus	1. AAMI ES-1 (1993)	1. Enclosure leakage test AAMI ES1 □5-3, 5-6	≻10,000uA	Equipment Accuracy: □1% of reading
			2. Patient lead leakage test AAMI ES1 □5-4	≻10,000uA	□1% of reading
		2. IEC 60601-1 (1988)	1.Enclosure leakage test, IEC60601□19	0-5000 uA	□1% of reading
			2.Safety Ground Leakage test, IEC60601 □19	0-5000 uA	□1% of reading
			3.Patient lead leakage test , IEC60601 □19.1E, 19.2A, 19.3, 19.4	0-200 uA	□1% of reading
			4.Impedance of protective earth test IEC60601□18f	0-20 ohms	□1% of reading

Discussions and Conclusions

The primary goal of this project is to further refine the infrastructure of our national management system for medical devices. To consolidate this idea, we are now trying to organize a union of certified medical device testing laboratory and dedicate to the quality assurance of both imported and domestic medical devices. To accommodate for the stringent needs of medical devices, a special requirement that take GLP into account will be incorporated in the near future. These include device classification, animal/clinical test protocol, data handling, etc. Through the learning processes of establishment of an ISO Guide 25 certified laboratory, the accordance of BME and CE can be further enhanced by the activities of design, verification, modification, and quality management system. It is a valuable experience to share with those who are interesting in such a program in the future.

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References

1. Lin, C.-W., Tseng, Y.-Z., "Biomedical Engineering : A New Program Integrating Medicine and Engineering at National Taiwan University", J. of Medical Education, 2:429-436 (1999).
2. Lin, C.-W., Chen, P.-Q., Chen, C.-T., Lu, C.-M., Chien, J.-H., Yang, C.-H., Huang, C.-K. "An Electromedical Safety Testing Laboratory in Compliance with ISO Guide 25", Annual Meeting of Chinese Biomedical Engineering Society, Tainan, Taiwan, R.O.C., 1999
3. Lin, C.-W., Chen, C.-T., Chen, P.-Q., Wang, C.-Y., Tseng, Y.-Z., Liu, H.-C., "The Refinement of Management System for the Testing of Medical Devices", Annual Meeting of Chinese Biomedical Engineering Society, Tainan, Taiwan, R.O.C., 1999
4. Lin, C.-W., Feng, P., Tang, Y.-Y. and Tseng, Y.-Z., 1998, "An Electrical Safety Analyzer for Standards of Electromedical Apparatus". Biomed. Eng. Appl. Basis Comm., 10:151-155