Recent Status and Topics on IEC 60601-1 series (Medical Equipments)

Satoshi Hirano[#1], Kowji Tanikawa[*2]

[#]*EMC Center, Fukuda Denshi CO.,LTD.*
305-1 Naka Shiroi-city Chiba, Japan
[1]satoshi.hirano@fukuda.co.jp

[*]*The Japan Federation of Medical Devices Associations*
3-2, Shimomiyabicho Shinjuku-ku Tokyo, Japan
[2] kowji.tanikawa@jfmda.gr.jp

***Abstract*— The typical standard used for EMC regulations for medical equipments in the world is IEC 60601-1-2. This standard is an EMC product family standard for medical equipments. There are some medical equipments to which particular standards for particular products, such as IEC 60601-2-XX, apply. Therefore, it shall be noted that tests differ according to the type of medical equipments.**

On the other hand, SC62A MT23 has been discussing a lot in order to issue the fourth edition of IEC 60601-1-2. It contains mainly two elements.

The first element is that the test levels are decided in consideration of the environment in which the medical equipments are being used.

The second element is that it includes safety and performance requirements.

In the new standard being established based on these two points, higher test levels will be required.

A questionnaire survey performed on manufacturers by JFMDA shows the substance of various problems in Japan.

When the fourth edition of IEC 60601-1-2 is being published, it will have a large influence on manufacturers not only in Japan, but all over the world.

Keywords:
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IEC 60601-2-XX
FDA
JFMDA
MHLW

I. INTRODUCTION

EMC regulations concerning medical equipments vary in each country.

In EU,EMC regulations have been incorporated in the MDD from 1998, and in the United States, the FDA controls EMC regulations. In Japan, the JFMDA has issued a guideline in 1997, and it has become a legal requirement by the MHLW since 2002. In either country, the typical standard used for EMC regulations for medical equipments is IEC 60601-1-2 which is collateral standard of IEC 60601-1.

II. MANUSCRIPTS

A. JFMDA Guideline

JFMDA issued the Guideline for manufacturers in 1997. The guideline requires new medical equipments to conform to IEC 60601-1-2:1993 from June, 1998. [1]
Finally, the total number of conforming equipments reached over 1500.

B. EMC regulations by the MHLW in Japan

The MHLW in Japan decided necessary to address the regulations of EMC, in consideration of the situation of various foreign countries.

In 2002, the MHLW has started to impose the regulations in stages, according to the classifications of the medical equipments. They have been imposed on class Ⅳ equipments since October 2003, on class Ⅲ equipments since April, 2004, and on class Ⅱ equipments since October, 2004. [2] Other regulations have been imposed on class Ⅰ equipments from April, 2008.

C. Applicable standards

The standard required by the regulations to be applied is mainly JIS T 0601-1-2, which is the EMC product family standard for medical equipments in Japan. JIS T 0601-1-2 is a standard translated into Japanese from IEC 60601-1-2, first edition, 1993. The second edition of IEC 60601-1-2 was published in 2001, and the amendment was published in 2004. The third edition was published in 2007 and is the latest standard. It was made from the second edition with editorial modifications. There is a big difference in the requirements between the first edition and the second edition. [3], [4], [5], [6]

MHLW admits IEC 60601-1-2 as well as JIS T 0601-1-2 from an international point of view.

Comparison of IEC 60601-1-2 between the first edition and the second edition is shown in TABLE Ⅰ.

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TABLE I
COMPARISON TABLE OF IEC 60601-1-2

Ref. standard	1st edition	2nd edition
CISPR11	Conducted emission 150kHz～30MHz	Conducted emission 150kHz～30MHz
CISPR11	Radiated emission 30MHz～1000MHz	Radiated emission 30MHz～1000MHz
IEC 61000-3-2		≦16A , 220V≦
IEC 61000-3-3		≦16A, 220V～250V
IEC 61000-4-2	Contact 3kV Air 8kV	Contact ±2,4,6kV Air ±2,4,8kV
IEC 61000-4-3	26MHz～1GHz 3V/m 80%AM	80MHz～2.5GHz 3,10V/m 80%AM
IEC 61000-4-4	Power line 1,2kV I/O cable 0.5kV	Power line ±2kV I/O cable 1kV
IEC 61000-4-5	Normal mode 1kV Common mode 2kV	Line-GND ±0.5,1,2kV Line-Line ±0.5,1kV
IEC 61000-4-6		150kHz～80MHz 3,10Vrms 80% AM
IEC 61000-4-8		3A/m
IEC 61000-4-11		＞95% 0.5cycle 60% 5cycle 30% 25cycle ＞95% 5seconds

D. Particular standards for particular products

There are particular standards for particular types of products, such as IEC 60601-2-XX. There are currently 51 particular standards, from IEC 60601-2-1 to IEC 60601-2-51. Some of these particular standards, contain deviation from IEC 60601-1-2, taking into consideration the characteristics and the feature of each products. In some cases, very high immunity test levels are required. For instance, magnetic field test level for infusion pumps is 400A/m.

E. IEC 60601-1-2 fourth edition

SC62A MT23 has been making a lot of discussions in order to issue IEC 60601-1-2, fourth edition. The fourth edition will be published in 2010. According to the matters discussed, there will be two major points different from the current contents. The test levels and methods will be different between the third edition and the fourth edition.

The first point is that the test levels will be decided in consideration of the environment in which the medical equipments being used.

The second point is that it will include safety and performance requirements. Concerning the safety requirements, immunity test levels will become high, taking into consideration the safety of the patients and the operators.

High immunity test levels are considered to be required for medical equipments used at home and transport locations. For example, the 30V/m radiated RF immunity test and the 25kV ESD test will be included in the fourth edition.

New additional standards and testing methods, such as MIL-STD,RTCA-DO160 and ISO 7637, as well as IEC 61000-4 series, will be included as well.

In addition, different immunity test level will be decided depending on the application points of EUT, so it will be a very confusing standard. The constitution of this standard will be closely related to CISPR24.

F. Some questionnaires survey to manufacturers by JFMDA

F-1.Manufacturers

The number of manufacturers of medical equipments in Japan is approximately 750, and a little less than 60% of those manufacturers are companies whose capital and sales are less than 50,000,000 yen. [7] [8]

The questionnaire survey performed by the JFMDA on manufacturers in 2005 shows that the main problem of addressing EMC is "cost." This shows a problem of the manufacturer's scale in Japan. [9]

F-2.Testing Laboratories

In 2007, The JFMDA carried out the questionnaire survey on testing laboratories in order to check the progress of addressing the EMC regulations demanded by MHLW. [10]

As a result, about 30 testing laboratories are able to perform the test of JIS T 0601-1-2.

However, the number of testing laboratories that can perform new additional standards as considered to be required in the fourth edition may be small. This is considered to be due to IT equipment being their main test object. It is considered likely that testing laboratories will not make good advances in adopting new facilities due to cost.

III. CONCLUSION

The scale of Japanese companies and the infrastructure of the testing laboratories are not necessarily sufficient. After the publication of the fourth edition of IEC 60601-1-2, the number of testing laboratories that can perform tests for medical equipments is likely to decrease, and, because of the amount of time required for the testing will increase significantly, the testing costs problem will have a big influence on manufacturers.

At any rate, it is necessary that the manufacturers collect new information of the standard as soon as possible, and establish the measuring technologies.

REFERENCES

[1] "The JFMDA Guidelines," JFMDA, Japan, 1997
[2] "MHLW EMC requirements for medical equipments", MHLW, Japan, 2002.
[3] "JIS T 0601-1-2," Japan Standards Association, July 2002.
[4] "IEC 60601-1-2" International Electrotechnical Commission, 1993.
[5] "IEC 60601-1-2" International Electrotechnical Commission, 2001.
[6] "IEC 60601-1-2 Am1", International Electrotechnical Commission, 2004.
[7] "Medical equipment industry investigation of actual conditions 2005", MHLW, 2005.

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[8] United States International Trade Commission "Competitive Conditions Affecting U.S. Trade in Japan and Other Principal Foreign Markets", Translated in Japanese by JFMDA, Japan, July 2008, pp.xvi
[9] "The questionnaire survey report of the manufacturer's EMC conformity situation," JFMDA, Japan, 2005
[10] "The questionnaire survey report of the testing laboratories situation," JFMDA, Japan, 2008

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