Achieving Medical Device EMC: The Role of Regulations, Standards, Guidelines and Publications

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Abstract: Many organizations around the world are currently working to improve EMC of electrical and electronic medical devices. Anecdotal evidence indicates that medical device manufacturers and healthcare providers are becoming increasingly knowledgeable and diligent regarding medical device EMI and EMC. Existing and new wireless services and other sources of EMI continue to proliferate; however at the same time, there is continuing development of regulations, standards, guidelines and publications that are intended to help prevent EMI and promote EMC and that can be applied to the safe use of RF sources and medical devices in hospitals. This paper provides a critical overview of the impact of such regulations, standards, guidelines and publications and their role in minimizing EMI malfunctions in healthcare. It also provides a bibliography that lists many of these important works.

INTRODUCTION

Considerable effort by many organizations around the world is currently devoted to improving the electromagnetic compatibility (EMC) of electrical and electronic medical devices. Existing and new wireless services and other sources of electromagnetic disturbance (EMD) continue to proliferate, e.g. existing and new wireless telephone services, digital television (DTV), wireless local area networks (LAN), “Bluetooth” equipment, and security systems. At the same time there is continuing development of regulations, standards, guidelines and publications that can be applied to the prevention of electromagnetic interference (EMI) and the promotion of EMC of electrical and electronic medical devices.

The current situation for medical device EMC in healthcare facilities is not ideal, but is improving. Healthcare organizations now have in their inventories and, due to financial constraints, will continue to use, older electrical and electronic medical devices that were not designed or tested for EMC. Such equipment is gradually being replaced with equipment for which the manufacturer claims compliance with current EMC standards. However, no EMC standard requires electronic medical equipment to be completely immune to every electromagnetic disturbance at any distance. Furthermore, compliance with EMC standards is usually demonstrated by type-testing, i.e. by testing only one prototype or a limited number of units. Performance of other units of the same model can differ. Also, electronic medical devices that would be totally immune to EMI would likely be too expensive or unusable (e.g. no displays or cables). Therefore, for the foreseeable future, healthcare organizations will need to manage EMC and the electromagnetic environment in their facilities. Ad hoc radiated RF immunity testing (e.g., [G3]) is a useful tool for assessing the effects of a particular RF source (e.g., a cellular telephone) on a particular medical device. This information can be applied to management of RF sources to assure their safe use in healthcare facilities, e.g. so that they are prohibited only in areas where such a prohibition is justified. Compliance by hospital staff, patients, and visitors with existing signage restricting such usage is difficult to enforce, and much of this signage has the limitation that it does not convey to staff, patients, and visitors that they should turn their cellular telephones off in restricted areas. As a result, medical device EMI incidents caused by cellular telephones continue to be reported [P31]. Healthcare organizations should avail themselves of existing EMC/EMI information resources so that meaningful policies and procedures for managing the electromagnetic environment of electronic medical devices in healthcare facilities can be developed and implemented.

This paper will overview significant past, recent, and ongoing activity in the development of regulations, standards, guidelines and publications that have reduced the risk of EMI malfunctions and that have promoted medical device EMC in healthcare environments. Some of the major contributions are discussed in this paper, and many more are listed in the Bibliography.

REGULATIONS AND GUIDELINES

Many organizations have promulgated regulations and guidelines that have significantly impacted medical device EMC (e.g., European Union (EU) and member nations, the U.S. Federal Communications Commission (FCC), and the U.S. Food and Drug Administration (US FDA) Center for Devices and Radiological Health (CDRH). Industry Canada and the Medical Devices Bureau of Health Canada).

The regulatory activities that have had the greatest impact on medical device EMC are the European EMC Directive and the EMC requirements of the European Medical Device Directive. These are mandatory EMC requirements for medical devices intended for sale in Europe. The requirements led to significantly increased activity in EMC standards, much of which is still ongoing.

In the U.S., the FCC regulates licensed and unlicensed radio-frequency (RF) emitters. In response to industry assurances that electromagnetic emissions were not a problem for medical devices, it exempted most electrical and electronic medical devices from emissions requirements in 1980 [P45]. Regarding electromagnetic immunity, the FCC has the authority to regulate it only for home electronic equipment, and the FCC has chosen instead to encourage voluntary immunity standards for such equipment. Recently, the FCC promulgated regulations establishing a Wireless Medical Telemetry Service (WMTS). The importance of this cannot be overstated. For years, medical telemetry operated as a secondary user of the RF spectrum, and keeping a telemetry system working properly in these frequency bands in a healthcare facility could often be difficult. The FCC action [R3] was driven primarily by an EMI incident and the advocacy and hard work of the AHA/ASHE (see Table 2). The WMTS regulations specify RF spectrum in which medical telemetry is a primary user, and also make provisions for frequency coordination. Further information regarding wireless medical telemetry is presented by other authors in the current special session.

In the U.S., the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) regulates the manufacture and sale of medical devices and electronic products that emit radiation. The regulations promulgated by the FDA/CDRH that have had the most significant impact on medical device EMC include
mandatory reporting by manufacturers and by user facilities of medical device problems [R4]. "Recognition" of voluntary consensus mandatory reporting by manufacturers and by user facilities of regulation [R5]. The first edition of IEC 60601-1-2 [S6] was "recognized" by FDA/CDRH in 1998. This enables manufacturers of applicable medical devices who reference the standard in their premarket submissions to the FDA to provide a declaration of conformity and summary information in lieu of a complete EMC test report. (Restrictions are listed under "Extent of Recognition" in the Supplementary Information document for the standard [W7].) Several recent CDRH medical device guidance documents reference IEC 60601-1-2.

**STANDARDS AND GUIDELINES**

The most significant standards activities pertaining to EMC of electrical and electronic medical devices have been conducted under the auspices of the organizations listed in Table 1. CDRH staff have made significant contributions in the development of medical device EMC standards and test methods.

**Table 1: Organizations that have developed standards that have fostered EMC in healthcare** (see Bibliography for selected individual references)


Considerable effort has gone into the development of IEC and ISO standards applicable to medical devices and EMC. Most CENELEC standards (European Norms or ENs) that are applicable to medical device EMC are based on IEC standards. However, the mandatory nature of the EU directives and their implementation by the member nations has had the result that medical device manufacturers filing for clearance in the U.S. appear to be certifying compliance with the European Norms (ENs) more than any other standards. For EMC of electrical and electronic medical devices, the EN equivalent of IEC 60601-1-2 appears to be cited most often.

IEC standard 60601-1-2 specifies EMC requirements and tests for medical electrical equipment. The first edition was published in 1993. The second edition has been under development since 1995, and publication is projected for mid-2001. The second edition is expected to have a significant impact on EMC of medical devices in healthcare facilities. In addition to specifying more stringent electromagnetic immunity requirements and additional tests, the second edition requires manufacturers to disclose much more information about the electromagnetic characteristics of their devices than most have in the past, including relatively detailed guidelines for management of the electromagnetic use environment of the product.

IEC 60601-1-2 is based on CISPR emissions standards and "Basic" EMC immunity standards developed by IEC Technical Committee (TC) 77, EMC. IEC standards generally can be categorized as one of the following types: Basic, Generic, Product Family, or Product. Basic standards specify test methods that can be referenced by the other types. Generic standards apply to products for which there is no product family or product standard. Product Family standards apply to a group of equipment types sharing common characteristics, e.g. medical electrical equipment. Product standards apply to a particular type of equipment, e.g. electrocardiographs. The hierarchy of standards under the jurisdiction of TC 62, Electrical Equipment in Medical Practice, is shown in Figure 1. IEC 60601-1 [S4], the "parent standard," is a Product Family standard for medical electrical equipment. The Collateral Standards, IEC 60601-1-X, of which IEC 60601-1-2 is one, add requirements to IEC 60601-1 and also apply to the product family. The IEC 60601-2-X standards, known as "Particular" or "Part two" standards, are Product Standards, e.g. IEC 60601-2-25, Particular requirements for the safety of electrocardiographs. They supplement, and in some cases substitute for, requirements of the Product Family Standard. The IEC 60601-3-X standards, Product Standards for essential performance of particular types of medical electrical equipment, will likely be absorbed into the "Part two" standards when they are harmonized with the third edition of IEC 60601-1 [S5], which includes requirements for essential performance as well as safety.

Standards and guidelines developed by CDRH include MDS-201-0004 [G7] and the Reviewer Guidance for Premarket Notification Submissions, November 1993, Anesthesiology and Respiratory Devices Branch [G8]. For many years, MDS-201-0004 was used by some medical device manufacturers as a voluntary EMC standard. The quasi-static test specified for respiratory and anesthesiology devices in [G8] was developed by CDRH engineers. It is not duplicated in any other standard and is useful for testing immunity of high-gain circuits to movement of electrostatically charged objects and people.

![Figure 1. The IEC 60601 family of standards](image)

Technical Information Report (TIR) 18 [G1], developed by the AAMI EMC Committee, contains comprehensive recommendations and guidelines for management of EMC in healthcare facilities and provides a model policy for EMC management, with guidance in customizing the policy for an individual healthcare organization. It should have made a significant impact on medical device EMC; however, it has not been sufficiently well disseminated to have the intended effect.

Recommended practice ANSI C63.18 [G2] is increasingly being used for medical device ad hoc radiated RF immunity testing. It was inspired by the pioneering ad hoc testing described by M.L. Rice and J.M. Smith in "Study of Electromagnetic Interference Between Portable Cellular Phones and Medical Equipment," presented at the 1993 Canadian Medical and Biological Engineering Conference, and also by Tan [P43] and Segal [P62]. The C63.18 recommended practice contributed to prevention of patient injury when it was used to discover RF susceptibility of a defibrillator. C63.18 ad hoc testing revealed that unintended discharge could be caused by a paging

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1 Thinh Nguyen, FDA/CDRH, private communication, April 2000.
transmitter. Furthermore, researchers are increasingly reporting that they are using C63.18 in their ad hoc testing ([P5], [P33], [P58], [P78]). It has even been used to test non-medical systems such as integrated circuit manufacturing equipment and milk pasteurization equipment.

**Publications**

EMC education has been widely recognized as a highly effective means of fostering EMC in healthcare, and EMC publications are a cost-effective way of achieving EMC education. In addition to the standards, guidelines, and regulations already mentioned, many publications (see Table 2) have had a significant impact on medical device EMC. Such publications have also led to numerous other significant medical device EMC activities. While it is not possible to list them all, the high level of activity in medical device EMC is evidenced by the sampling that appears in the Bibliography.

A publication that can be expected to have a significant impact on medical device EMC in healthcare facilities is a Report of the American Medical Association (AMA) Council on Scientific Affairs [P49]. ([W2] is a summary of the report.) It contains recommendations from doctors to healthcare staff and administrators for achieving EMC in healthcare facilities, and also concurs with the recommendations of AAMI TIR-18 [G1] and the McGill Group on EMC [P66].

**Table 2: Publications and organizations whose publications have fostered EMC in healthcare (see Bibliography for selected individual references)**

- **AAMI/FDA conference proceedings**
  - American Society for Healthcare Engineering (ASHE) of the American Hospital Association (AHA)
  - Biomedical Instrumentation & Technology (BIT), published by AAMI Compliance Engineering
  - The U.S. Federal Communications Commission
  - The U.S. FDA Center for Devices and Radiological Health
  - The U.S. Winchester Engineering and Analytical Center (WEAC)
  - Health Canada Medical Devices Bureau
  - Health Devices, published by ECR1
  - IEEE EMC Symposium Proceedings
  - IEM (The International Journal of EMC)
  - The Journal of Clinical Engineering
  - McGill Biomedical Engineering Group on EMC
  - Proceedings of the Round Table on EMC in Health Care (Ottawa, Ontario, Sept. 1994)
  - Proceedings of the Workshop, Electromagnetic Interference and EMC in Health Care Facilities (Edmonton, Alberta, 1987)
  - The University of Oklahoma Center for the Study of Wireless EMC
  - The Internet is an outstanding communication medium and it will have a great impact on medical device EMC. Healthcare organizations are encouraged to review the publications and guidance on the EMC web pages listed in the Bibliography.

**Recommendations**

Healthcare organizations should review and consider existing information resources on management of EMC in healthcare facilities, particularly the guidance provided by AAMI TIR-18 [G1], C63.18 [G2], the U.K. MDA [W8], ECRI [P20], and the AMA report on the use of wireless RF equipment [P49]. Once the second edition of IEC 60601-1-2 [S5] is in use, the EMC guidance it requires to be supplied by medical device manufacturers with new medical electrical equipment should also be considered. Appropriate management of wireless RF sources and the EMC of all electrical equipment in healthcare facilities will help to achieve the convenience and productivity that wireless equipment can offer while assuring the safe use of electrical and electronic medical devices.

**Conclusions**

The contributions of only a few of the many organizations around the world that are currently working to prevent EMI and assure EMC of electrical and electronic medical devices through development of regulations, standards, guidelines and publications have been overviewed. The net impact of the proliferation of wireless equipment and services and the many ongoing medical device EMC activities is difficult to assess. Anecdotal evidence indicates that medical device manufacturers and healthcare providers are increasingly knowledgeable and diligent regarding medical device EMI and EMC. While the tremendous amount of activity in medical device EMC appears to have kept constant, or reduced, the occurrence of EMI problems, these problems have not been eliminated. There is more yet to be done. As always, manufacturers of electrical and electronic medical devices should continue working for lower electromagnetic emissions and higher immunity of their products. EMC engineers will play a key role in such activities. However, until all medical devices in use are immune to any expected electromagnetic disturbance at any distance, purchasers and users of electronic medical devices must continue to be vigilant regarding EMC and the electromagnetic use environment, to help prevent medical device EMI problems.

**Bibliography**

Guidelines


Stephen Juett, Baylor University Medical Center, private communication, January 2000.


4 Available as Accession Number PB271635 from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161, USA.


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Publications


Regulations

[R1] EU EMC Directive

[R2] EU Medical Device Directive


Standards


Internet web pages


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7 In preparation. IEC 62A/321/CDV (2000-02) and its revision, IEC 62A/XXX/FDIS (number not known at the time of preparation of this paper).

8 MIL-STDs are available from Defense Printing Service Detachment Office, 700 Robbins Avenue, Philadelphia, PA 19111-5094, USA