Technical Information Report

AAMI TIR18:2010

Guidance on electromagnetic compatibility of medical devices in healthcare facilities

Association for the Advancement of Medical Instrumentation

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AAMI Technical Information Report

AAMI TIR18:2010
(Revision of AAMI TIR18:1997)

Guidance on electromagnetic compatibility of medical devices in healthcare facilities

Approved 8 March 2010 by
Association for the Advancement of Medical Instrumentation

Abstract: This AAMI Technical Information Report (TIR) provides information, guidance, and general recommendations regarding electromagnetic compatibility (EMC) of medical devices and the use of RF wireless technology in healthcare facilities to promote patient safety. It is intended to provide a broad range of information about EMC of medical devices for clinical and biomedical engineers and other technical personnel; healthcare administrators, including heads of hospital departments; medical staff; and healthcare associations. The information herein will help healthcare organizations evaluate their electromagnetic (EM) environment and implement actions needed to minimize electromagnetic interference (EMI) problems and manage the EM environment, including wireless RF sources. Although this TIR focuses on healthcare facilities, the home environment is briefly addressed. Management of the electromagnetic environment and management of medical devices for EMC are discussed, as are the following subjects: assessment of the electromagnetic environment; investigation and reporting of EMI problems; selected case studies in EMI problems; site selection, design, and construction of new facilities; a model EMC and wireless policy and guidance for developing EMC and wireless policies; and principles of electromagnetic energy and interference mechanisms. Definitions of terms and a bibliography are also provided.

Keywords: ad hoc testing, cellular telephones, conducted immunity, electromagnetic compatibility, electromagnetic disturbance, electromagnetic interference, electrostatic discharge, EMC, EM disturbance, EMI, ESD, mobile communications, mobile telephones, radiated immunity, wireless local area network (LAN)

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NOTE—Following each section cited below is a code to indicate which of the following readers should pay particular attention to that section. An acronym/abbreviation will be used for convenience:

Healthcare administrators, including hospital heads (ADMIN)
Patient safety/risk management personnel (PSRM)
Clinical/biomedical engineers and other technical personnel (TECH)
Medical staff (MED)
Healthcare associations (HCA)
All readers (ALL)

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International designation	U.S. designation	Equivalency
IEC 60601-1:2005 Technical Corrigendum 1 and 2	ANSI/AAMI ES60601-1:2005 and ANSI/AAMI ES60601-1:2005/A2:2010 ANSI/AAMI ES60601-1:2005/C1:2009 (amdt)	Major technical variations C1 Identical to Corrigendum 1 & 2
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007	Identical
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IEC 60601-2-19:2009	ANSI/AAMI/IEC 60601-2-19:2009	Identical
IEC 60601-2-20:2009	ANSI/AAMI/IEC 60601-2-20:2009	Identical
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IEC 60601-2-47:2001	ANSI/AAMI EC38:2007	Major technical variations
IEC 60601-2-50:2009	ANSI/AAMI/IEC 60601-2-50:2009	Identical
IEC 80601-2-30:2009 and Technical Corrigendum 1	ANSI/AAMI/IEC 80601-2-30:2009 and ANSI/AAMI/IEC 80601-2-30:2009/ C1:2009 (amdt) – consolidated text	Identical (with inclusion) C1 Identical to Corrigendum 1
IEC 80601-2-58:2008	ANSI/AAMI/IEC 80601-2-58:2008	Identical
IEC/TR 60878:2009	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2009	ANSI/AAMI/IEC TIR62296:2009	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
IEC/TR 62354:2009	ANSI/AAMI/IEC TIR62354:2009	Identical
IEC/TR 80002-1:2009	ANSI/IEC/TR 80002-1:2009	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005/(R)2010	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2010	Identical
ISO 7199:2009	ANSI/AAMI/ISO 7199:2009	Identical
ISO 8637:2004	ANSI/AAMI RD16:2007	Major technical variations
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ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006	Identical
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ISO 10993-7:2008	ANSI/AAMI/ISO 10993-7:2008	Identical
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ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical
ISO/TS 11135-2:2008	ANSI/AAMI/ISO TIR11135-2:2008	Identical
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ISO 11138-3: 2006	ANSI/AAMI/ISO 11138-3:2006/(R)2010	Identical
ISO 11138-4: 2006	ANSI/AAMI/ISO 11138-4:2006/(R)2010	Identical
ISO 11138-5: 2006	ANSI/AAMI/ISO 11138-5:2006/(R)2010	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005	Identical
ISO 11140-3:2007	ANSI/AAMI/ISO 11140-3:2007	Identical
ISO 11140-4:2007	ANSI/AAMI/ISO 11140-4:2007	Identical
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ISO/TS 17665-2:2009	ANSI/AAMI/ISO TIR17665-2:2009	Identical
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Association for the Advancement of Medical Instrumentation

AAMI Electromagnetic Compatibility Committee

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Foreword

The electromagnetic (EM) environment in modern healthcare facilities can be extremely variable, particularly as a result of the tremendous growth in radiofrequency (RF) wireless communications such as cellular telephones, wireless personal digital assistants (PDAs), and wireless local area networks (LANs). Electromagnetic compatibility (EMC) is the ability of a system or medical device to function satisfactorily in its electromagnetic environment without introducing intolerable EM disturbance to anything in that environment. Thus, EMC of medical devices must be an integral part of all health care wherever active medical devices and systems are deployed. Healthcare organizations must actively manage their equipment and RF wireless technology to ensure EMC and mitigate the risks of electromagnetic interference (EMI).

This edition of the TIR reflects the continuous efforts of concerned medical device users, healthcare professionals, regulators, and medical device manufacturers to disseminate information and recommendations for control of EMI caused by EM disturbance from a variety of sources. The first edition was developed by the AAMI Electromagnetic Compatibility Committee in response to interest and inquiries from clinical and biomedical engineers regarding the risks of radiated EMI that might be caused by RF transmitters (e.g., portable cellular telephones) and what could be done to mitigate those risks. It was inspired in part by Paperman, et al. (1994). This new edition focuses on updating the original information and recommendations and on distinguishing important points for consideration by both engineering/technical and nontechnical personnel who use and manage electrical and electronic systems in healthcare facilities.

The objective of this TIR is to convey important information about the potential risks of EMI and RF wireless technology and what can be done to reduce those risks while deploying increasingly sophisticated medical systems. A primary objective is to help clinical and biomedical engineers and other technical personnel assess the electromagnetic environment in individual healthcare facilities, implement actions needed to minimize EMI problems, promote EMC, and, thus, promote the safety of patients and staff. In addition, this TIR is intended to raise awareness about the risks and concerns surrounding EMC and RF wireless technology in healthcare facilities. To this end, the new edition of the TIR has been rearranged to make it easier for non-engineers to find and understand the recommendations for EMC and RF wireless technology. These recommendations are aimed at promoting understanding and communication among the vital components of the healthcare organization, including administrators, medical staff, risk managers, security personnel, physical plant staff, and patients.

This TIR includes specific recommendations regarding how to assess and manage the electromagnetic environment for EMC, recognize and report EMI incidents, and promote communication about EMC and RF wireless technology deployment and use. In addition, the TIR

a) describes a model EMC and wireless policy that can be tailored to meet the needs of an individual healthcare facility;

b) provides background information on electromagnetic energy and interference mechanisms;

c) discusses what might be done to promote EMC for existing equipment and facilities as well as for new equipment and facilities; and

d) includes case studies to illustrate the types of EMI problems that can occur.

Readers should pay particular attention to the sections noted in the table of contents as being of interest according to their role in the healthcare organization.

As used within the context of this document, “should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the technical information report. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

Suggestions for improving this TIR are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203.

NOTE—This foreword does not contain provisions of the AAMI Technical Information Report, *Guidance on electromagnetic compatibility of medical devices in healthcare facilities* (AAMI TIR18:2010), but it does provide important information about the development and intended use of the document.

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Guidance on electromagnetic compatibility of medical devices in healthcare facilities

1 Introduction and scope

Because the performance of electronic medical devices can be disrupted by electromagnetic (EM) energy, patient safety can potentially be put at increased risk because of the effects of electromagnetic interference (EMI). EMI is caused by an EM disturbance, which can be in the form of radiated disturbance (radio waves propagating through the air); conducted disturbance (radio waves induced on power or signal wires); AC power-line transients, surges, sags, and dropouts; and electrostatic discharge (ESD). Radiofrequency (RF) sources that emit various EM disturbances have proliferated in modern society, including healthcare facilities, creating the potential for EMI with electronic medical devices. Sources of EM disturbance include any product or device that uses electricity or can carry an electrical charge. Systems that can emit EM disturbances include, but are not limited to, the following:

a) Cellular telephones and other wireless communication devices
b) Two-way radios
c) Wireless barcode systems
d) Radiofrequency identification (RFID) systems
e) Security systems
f) Fire alarm systems
g) Nurse call systems
h) Heating, ventilation and air-conditioning (HVAC) systems
i) Motor controllers, including elevators and copiers
j) Medical devices

Concerns arise because the EM disturbance exposure might exceed the immunity designed into medical devices and systems and because some electronic medical devices currently in use have not been tested for immunity to EM disturbances. The risks faced by even those devices that comply with EMC standards seem to be increasing as the number of radio transmitter sources, including RF wireless technology, is dramatically increasing within and outside healthcare facilities. Numerous EMI incidents have been reported in the literature.

2 Definitions and abbreviations

For purposes of this TIR, the following definitions and abbreviations apply.

NOTE 1—Throughout this TIR, “cell phone” is used interchangeably with “mobile phone.” The preferable usage is “mobile phone” because “mobile phone” is the term commonly used internationally.

NOTE 2—References in brackets are the source of the definition.

2.1 ANSI: American National Standards Institute.

2.2 ASHE: American Society for Healthcare Engineering.

2.3 BP: Blood pressure.

2.4 CCU: Critical care unit.

2.5 CDMA: Code division multiple access.

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2.6 conducted emissions: Electromagnetic energy emanating from a product through a conductor by means of resistance, inductance, or capacitance.

NOTE—Conductors include AC power cords, metallic enclosures of a subsystem, and cables interconnecting subsystems or the patient to the product. Conducted emissions include power-line harmonics and RF energy commonly tested and specified in the frequency range of 150 kilohertz (kHz) to 80 megahertz (MHz).

[U.S. FDA, 2007]

2.7 CRT: Cathode ray tube.

2.8 CT: Computed tomography.

2.9 CW: Continuous wave.

2.10 degradation (of performance): Undesired departure in the operational performance of any equipment or system from its intended performance.

NOTE—The term “degradation” can apply to temporary or permanent failure.

[IEC 60050-161]

2.11 DC: Direct current.

2.12 DTV: Digital television.

2.13 ECG: Electrocardiography; electrocardiogram.

2.14 EEG: Electroencephalography; electroencephalogram.

2.15 electromagnetic compatibility: Ability of equipment or a system to function satisfactorily in its electromagnetic environment without introducing intolerable EM disturbance to anything in that environment.

[IEC 60050-161]

2.16 electromagnetic disturbance: Any electromagnetic phenomenon that could degrade the performance of equipment or a system.

NOTE—An EM disturbance could be an electromagnetic noise, an unwanted signal, or a change in the propagation medium itself.

[IEC 60050-161]

2.17 electromagnetic emission: Phenomenon by which electromagnetic energy emanates from a source.

NOTE—Electromagnetic emissions generally fall into two categories: conducted and radiated. Both types of emissions can occur simultaneously, depending on the configuration of the device.

[IEC 60050-161]

2.18 electromagnetic environment: Totality of electromagnetic phenomena existing at a given location.

[IEC 60050-161 and U.S. FDA (2007)]

2.19 electromagnetic interference: Degradation of the performance of equipment, a transmission channel, or a system caused by an EM disturbance.

[IEC 60050-161]

2.20 electrostatic discharge: Transfer of electric charge between bodies of different electrostatic potential in proximity or through direct contact.

[IEC 60050-161]

2.21 EM: Electromagnetic.

2.22 EMC: Electromagnetic compatibility.

2.23 EMG: Electromyography; electromyogram.

2.24 EMI: Electromagnetic interference.

2.25 ER: Emergency room.

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2.26 ESD: Electrostatic discharge.

2.27 ESU: Electrosurgical unit.

2.28 Far field: Distance from the antenna of an RF transmitter that is more than several wavelengths of the transmit frequency. (See A.4.2.)

[IEC 60050-161]

2.29 FCC: Federal Communications Commission.

2.30 FOI: Freedom of Information.

2.31 GSM: Global system for mobile communications.

2.32 HVAC: Heating, ventilation, and air conditioning.

2.33 ICD: Implantable cardioverter defibrillator.

2.34 ICU: Intensive care unit.

2.35 IEC: International Electrotechnical Commission.

2.36 IEEE: Institute of Electrical and Electronics Engineers.

2.37 immunity: Ability of equipment or a system to perform without degradation in the presence of an electromagnetic disturbance.

NOTE—Immunity applies to radiated and conducted disturbances and ESD.

[IEC 60050-161]

2.38 ISM: Industrial, scientific, and medical.

2.39 ISO: International Organization for Standardization.

2.40 IV: Intravenous.

2.41 LAN: Local area network.

2.42 latency: Time it takes for a unit of information to cross a wireless link or network connection from sender to receiver.

[U.S. FDA, 2007]

2.43 MRI: Magnetic resonance imaging.

2.44 NBICU: Newborn intensive care unit.

2.45 Near field: Distance from the antenna of an RF transmitter that is less than several wavelengths of the transmit frequency. (See A.4.2.)

[IEC 60050-161]

2.46 NPF: No problem found.

2.47 OR: Operating room.

2.48 PACS: Picture archiving and communication system.

2.49 PC: Personal computer.

2.50 PCA: Patient-controlled analgesic.

2.51 PCS: Personal communication services.

2.52 PDA: Personal digital assistant.

2.53 Quality of Service (QoS): Agreed-upon level of performance in a data communications system or other service.

NOTE—QoS typically encompasses multiple performance parameters, such as reliability of data transmission, transfer rate, error rate, and mechanisms and priority levels for time-critical signals.

[U.S. FDA, 2007]

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2.54 radiated emissions: Electromagnetic energy emanating from a device and propagating through space or a medium (which can affect the distance and direction of propagation).

NOTE—Radiated emissions include both intentional emissions (e.g., radio transmissions carrying information) and unintentional emissions (e.g., emissions associated with electrically-powered equipment such as motors, power supplies, and computer components).

[U.S. FDA, 2007]

2.55 radiofrequency: Frequency in the portion of the electromagnetic spectrum that is between the audio frequency portion and the infrared portion.

NOTE—The present practical limits of radio frequency are roughly 9 kHz to 3,000 gigahertz (GHz).

[ANSI C63.14]

2.56 radiofrequency interference: Type of EMI that results from radiated emissions at one or more radio frequencies.

[U.S. FDA, 2007]

2.57 radiofrequency wireless medical device: Medical device that includes at least one function that is implemented using RF wireless communications.

NOTE—Examples of functions that can be implemented wirelessly include data transfer, device control, programming, power transmission, remote sensing and monitoring, and identification.

[U.S. FDA, 2007]

2.58 RF: Radiofrequency.

2.59 RF wireless: Transmission of signals or power using RF electromagnetic waves, rather than wire or optical fibers.

2.60 RFI: Radiofrequency interference.

2.61 S_pO_2: Saturation pressure of oxygen.

2.62 SMDA: Safe Medical Devices Act.

2.63 susceptibility: Inability of equipment or a system to perform without degradation in the presence of an EM disturbance.

NOTE—Susceptibility is a lack of immunity. (Immunity is the preferred international term for this aspect of EMC.)

[IEC 60050-161]

2.64 TSP: Twisted shielded pair.

2.65 UPS: Uninterruptible power supply.

2.66 vulnerability: See **susceptibility**.

2.67 WEP: Wired equivalent privacy.

2.68 wireless coexistence: Ability of one wireless system to perform a task in a given shared environment in which other systems (in that environment) are able to perform their tasks and might or might not be using the same set of rules.

[U.S. FDA, 2007]

NOTE—For more information, see IEEE 802.15.2.

2.69 WMTS: Wireless Medical Telemetry Service.

2.70 WPA: Wi-Fi protected access.

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3 General recommendations

3.1 Overview

Because the use of electrical and electronic medical devices and systems and RF wireless technology in health care has become nearly universal, the EMC recommendations provided in this section apply to all healthcare organizations. Careful consideration of this TIR in its entirety will help healthcare personnel and others understand this important issue. For the recommendations to be effective, coordination and communication are imperative, especially among the groups listed in Table 1.

Table 1—Groups requiring coordination and communication regarding medical device EMC and RF wireless technology for assurance of patient and staff safety

Risk management and patient safety
Administration
Clinical/biomedical engineering
Information technology/systems, including telecommunications
Medical staff
Security
Procurement/purchasing, including materials management
Facility engineering and management

For more complete information on the topics in the following recommendations, the sections referenced should be consulted. The recommendations should all be read and applied. The sequence and numbering of the recommendations does not imply a priority.

3.2 Focal point for EMC

An EMC and Wireless Coordinator or Manager should be designated for EMC, EMI mitigation, RF wireless technology, and EMC and RF wireless technology education and training within the healthcare organization. This person should be familiar with the entirety of this TIR in depth—or seek assistance from those who are—in order to work with the personnel listed in Table 1, as needed, in solving EMC-related issues. (See Annex C.)

3.3 EMC and RF wireless technology coordination

The coordination of EMC and RF wireless technology should become a permanent responsibility of the healthcare organization's Safety Committee. (See Annex C.)

3.4 Policies and procedures

The healthcare administration or its designee (e.g., the Safety Committee) should establish EMC and RF wireless technology policies and procedures. (See Annex C.)

3.5 Resources

The healthcare administration should provide the resources for clinical/biomedical engineering and other responsible staff to obtain the requisite education, equipment, and tools to implement the recommendations of this TIR.

3.6 Ad hoc immunity testing

Ad hoc RF immunity testing according to ANSI C63.18 should be considered to assess how specific transmitters could affect specific medical devices. Policies and procedures for EMI mitigation should be based on objective information, such as that obtainable by ad hoc RF immunity testing. (See subsection 6.4.)

3.7 Ad hoc immunity testing (close distance)

Ad hoc RF immunity testing at close distance should be considered to estimate the EMI risk in uncontrolled environments (e.g., public areas in which both critical medical devices and RF sources are permitted, areas in which the staff uses cellular/personal communication services [PCS]/mobile phones that are not power-controlled within the facility, home-care environments in which electronic medical devices are used). (See subsection 6.4.)

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3.8 Coordination of equipment purchase, installation, servicing, and management

The purchase, installation, servicing, and management of all electrically-powered equipment used in the facility should be coordinated to ensure EMC and the safe and reliable use of RF wireless technology. All groups listed in Table 1 should be aware of the possibility of equipment interactions and the need for coordination. (See Annex C.)

3.9 Standards

Electrically-powered medical devices on hand and being considered for purchase should meet applicable EMC standards. (See subsection 6.2.)

3.10 Education

Education should be provided to staff; visitors; patients, including home-care patients; and fire, emergency, and law enforcement personnel regarding the nature of EMI and how they can recognize and help prevent it. (See Section 9.)

3.11 EMI problems

EMI problems should be reported to the manufacturer and to regulatory authorities. (See subsection 7.3 and Annex C.)

3.12 RF transmitters

RF transmitters purchased for use in the facility should have the lowest possible output power rating necessary to accomplish the intended purpose and should not exceed the input power specifications of other system receivers within the facility. (See subsection 5.3.3.3.4.)

3.13 List of RF sources

The EMC and Wireless Coordinator or committee should generate and maintain a list of all intentional RF sources inside and within a one-mile radius of the healthcare facility. The list should identify the operating frequencies and locations of these sources. (See Sections 4 and 5.)

3.14 RF spectrum usage

The RF spectrum usage of all intentional RF transmitters in the facility should be managed, to the extent possible, to avoid conflicts. (See subsections 4.2 and 5.2.)

3.15 Electronic medical devices used near high-power RF sources

Electronic medical devices used in proximity to known high-power RF sources should be suitable for these environments. An RF survey might be necessary to assess these environments. Examples of such environments include areas near ambulance radios and near actively used electrosurgical equipment. (See 3.19, 4.4, and 6.2.)

3.16 EMC test reports

The EMC and Wireless Coordinator should request EMC test reports from equipment manufacturers if the test reports are needed in addition to the EMC information already provided. The EMC and Wireless Coordinator should request that updates to this information be provided whenever new test results show changes in or new information about EMC performance pertinent to the use of a device in the healthcare environment. (See subsection 6.2.)

3.17 Facility considerations

EMC should be considered in the site selection, design, construction, and layout of healthcare facilities (Section 8.)

3.18 “No problem found”

Healthcare organizations servicing medical devices should consider tracking “no problem found” (NPF) service calls by the location, date, and time of the reported malfunctions. Such tracking can help associate malfunctions with sources of EM disturbance. (See 6.3.3.)

3.19 EMC professionals

The healthcare organization should consider obtaining the services of an EMC professional for assistance in characterizing the electromagnetic environment, solving specific problems, and/or educating staff. (See Sections 4, 5, 7, 9, and Annex C.)

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4 Assessment of the electromagnetic environment in existing facilities

4.1 Overview

To control EMI and promote the safe use of RF wireless technology, it is essential to assess the electromagnetic environment. Sources of EM disturbances within and outside the healthcare facility should be identified, as well as the areas within the facility where patients could be most adversely affected by EMI. The EMC and Wireless Coordinator should have thorough knowledge of the electromagnetic environment within the facility and be the gatekeeper in determining the safety of existing and future RF sources around medical instrumentation. For the assessment of the electromagnetic environment, it might be advisable to seek the assistance of EMC professionals.

4.2 Identification of RF sources

The EMC and Wireless Coordinator should identify the RF sources within and nearby the facility. A list of all known sources should be compiled, including both intentional sources and unintentional sources. The list will be helpful in RF spectrum management and in researching and troubleshooting any problems that might be related to EMI.

Intentional RF sources use RF energy for communications, control, or treatment of material or patients and can be categorized as shown below (the examples are not meant to be exhaustive):

a) On-site portable and mobile RF sources

- hand-held transceivers (walkie-talkies and Family Radio Service [FRS] transceivers)
- cellular telephones
- pharmaceutical robots
- RFID tags and readers
- wireless LANs
- medical telemetry transmitters
- two-way pagers
- personal digital assistants (PDAs)
- wireless bar-code readers
- wireless speakers
- printers, keyboards, mice
- video games
- electrosurgical devices
- RF ablation/lesion devices
- wireless footswitches
- Bluetooth devices
- wireless medical devices

b) On-site fixed RF sources

- paging transmitters
- repeaters for commercial and safety service portable and land mobile communications
- mobile (cellular and PCS) communications equipment, including base stations
- wireless access points
- RFID readers
- microwave radio links
- time clocks
- broadband over power line

c) Outside portable and mobile RF sources likely to be in the vicinity

- two-way radios in ambulances and police and fire vehicles
- taxi and shuttle bus radios
- radios in government and military vehicles
- radars

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d) Outside fixed RF sources

- transmission towers for cellular phones, radio, television, WiMax, clock synchronizers, and other communication services
- neighboring facilities employing wireless transmitters
- radars

The EMC and Wireless Coordinator should prepare a list of RF sources in each of these categories and include the following information: frequency, location, output power, power limitations, input sensitivity, and person responsible for using and maintaining the sources. For each on-site source, the EMC and Wireless Coordinator should also have a copy of the operator's manual or instructions for use; alternatively, the list should include the location where the manual is kept. The list should be updated as new communications equipment is brought into service.

Unintentional RF sources produce RF energy as a byproduct of their normal operation. Electrically-powered equipment, including battery-powered equipment, can be an unintentional RF source. Some examples are as follows (the examples are not meant to be exhaustive):

a) Medical devices

- imaging systems (X-ray, computed tomography [CT], magnetic resonance imaging [MRI])
- defibrillators
- patient monitors
- hemodialysis machines

b) Office equipment

- computers
- paper shredders
- fax machines, scanners, printers
- copiers
- uninterruptible power supplies

c) Electronic games

d) Mp3 players

e) Radio and television receivers

f) Cable television wiring and control systems

g) Fluorescent lamp ballasts and dimming controls

h) High-voltage relays

i) Elevator motors, relays, circuitry, and controls

j) HVAC and fire alarm systems; circuitry and control units

k) Motors of all types (e.g., motors in cleaners, floor scrubbers, cordless tools)

l) Dimmer switches of all types

m) Patient-room amenities

- hair dryers
- electric toothbrushes

Conducted EMI can occur any time there is a complete path (e.g., over the power line) from an offending device to a susceptible device. Devices that are connected to the same patient at the same time can interfere with each other via the conductive path provided by the patient. EM disturbances can be particularly intense in proximity to equipment that generates or uses high voltages or currents.

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4.3 Identification of areas where critical medical devices are used

Areas where critical medical devices are used should be identified to facilitate EMI risk assessment and EMC management. As the term is used in this TIR, critical medical devices are devices (either therapeutic or diagnostic) that can immediately affect the physiological state of a patient. Clinical/biomedical engineering personnel should work with the EMC and Wireless Coordinator and the Safety Committee to ensure that all such areas are identified, and the list should be reviewed periodically. Examples of areas where critical devices are used include the following (the examples are not meant to be exhaustive):

a) Intensive care units (ICUs)

b) Critical care units (CCUs)

c) Operating rooms (ORs)

d) Recovery rooms

e) Newborn nurseries

f) Pediatric and newborn intensive care units (NBICUs)

g) Labor and delivery rooms

h) Emergency rooms (ERs)

i) Diagnostic areas (e.g., electroencephalography [EEG] units, electromyography [EMG] units, imaging units, clinical and diagnostic laboratories)

j) Dialysis clinics

k) Cancer drug therapy clinics

l) Outpatient surgery centers

m) Cardiac centers

The major goal of identifying these areas is to establish control of the RF electromagnetic environment and of the EMI risks to specific medical devices used there. Some areas could be more difficult to control than others (e.g., areas used by or accessible to the general public). In some areas, ongoing monitoring of compliance with the healthcare organization's EMC and RF wireless technology policies and procedures might be required. Also, personnel using RF wireless communications equipment in these areas might require special training.

4.4 Ambient electromagnetic measurements

Measurements of the ambient electromagnetic spectrum, especially in wireless communications bands, should be considered for areas where critical devices are used in order to determine the existing frequencies and intensities of radiated and power-line electromagnetic energy within those areas. In such areas, both conducted and radiated RF disturbances might exist.

Because of the mobile nature of some devices and operational duty cycles, some sources of radiated and conducted RF could be intermittent. Data on the existing electromagnetic environment can be helpful in solving existing and future EMI problems and in analyzing the potential impact of new equipment. For information on prior surveys of electromagnetic environments in healthcare facilities, see Annex D.

Accurate measurements of the electromagnetic environment require specialized test equipment and skills. Complete assessment over time and space is difficult and extremely complex. It is not unusual for different surveys of the same environment to yield different results. If environmental measurements do not identify specific problematic RF sources, the absence of EMI problems is not guaranteed. Ambient electromagnetic measurements are most useful in characterizing RF fields and power-line coupling from outside fixed sources and in identifying recurring interference problems.

Simple field-strength meters might be less expensive than spectrum analyzers, but they provide a limited amount of information and they are considerably less accurate. Spectrum analyzers provide more complete and accurate information on frequencies, signal amplitudes, and field strengths; however, they are expensive (more than $10,000 each). Alternatives to purchase of a spectrum analyzer by a healthcare organization include rental, pooling resources with other organizations, and arrangements with manufacturers or wireless service providers to use their equipment on a temporary basis. A good understanding of spectrum analysis is required when selecting spectrum analyzer

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features useful for detecting different types of signals. Environmental field-strength site surveys should be performed in accordance with IEEE 473 (see, in particular, section 5.3, “Interior Locations”).

If conducted RF is suspected as the cause of EMI problems, RF on cables, including power lines, can be measured with a current probe and a spectrum analyzer. This technique is noninvasive because the current probe attaches around the outside of the cable. Specifications for a current probe that can be used to measure conducted RF can be found in Clause 5.1 of CISPR 16-1-2. For further information on investigating conducted EMI problems, see subsection 7.2. For examples of conducted EMI problems, see B.7 and B.8.

NOTE—In general, such measurements should be performed by those familiar with the instrumentation and with making such measurements.

5 Management of the electromagnetic environment

5.1 Overview

Effective management of the electromagnetic environment is crucial to the prevention of EMI problems. A model policy that might be useful in the management of the electromagnetic environment is provided in Annex C.

5.2 RF spectrum management

To avoid conflicts, RF spectrum usage of all intentional RF transmitters in the facility should be managed to the extent possible. Frequency information for potential new equipment purchases should be compared to the list identified in 4.2 and managed as appropriate for the technology type.

Installation of new systems should be managed to prevent interference with existing equipment. Antenna and access point locations should be planned so that proximity interference can be avoided. Channel bandwidth and transmitter programming should be managed so as to avoid conflict with existing systems. Other strong signals in the vicinity should be evaluated for possible effects on newly installed receivers. The equipment operator’s manual or user's manual often contains useful guidance on this subject.

For Wireless Medical Telemetry Service (WMTS) equipment, the American Society for Healthcare Engineering (ASHE) was designated by the Federal Communications Commission (FCC) as the Frequency Coordinator. ASHE performs this role in partnership with Comsearch. Authorization to operate WMTS equipment and frequency coordination information can be obtained on-line at http://www.ashe.org. ASHE’s services include registration, access to a database of existing WMTS assignments, available frequency bands, and the locations of digital TV stations by geographic area. Information on U.S. government radioastronomy stations and military radar systems is also provided. Comsearch can provide detailed interference analyses and recommendations for frequency selection (http://www.comsearch.com). Even when the healthcare organization has information on available frequency bands, it might be necessary to coordinate with other healthcare facilities nearby. Such coordination is most easily accomplished by sharing frequency lists.

As an example of the importance of RF spectrum management, some WMTS systems using differing technologies, especially channelized and frequency-hopping systems, have been known to interfere with each other. This interference usually occurs when different departments of a facility install systems from different manufacturers. It is imperative that hospitals understand the problem and agree to mitigation strategies before deploying systems using different technologies. Mitigation after installation usually requires one or both of the systems to be constrained in frequency use, which almost always results in a loss in capacity of one or both systems.

5.3 On-site portable and mobile RF sources

5.3.1 General considerations

Technical and procedural strategies should be formulated to manage the use of on-site portable and mobile RF wireless communications equipment and should take into account the RF sources identified (see 4.2), the areas where critical medical devices are used (see 4.3), the EMC specifications or ad hoc test results for the medical equipment, and the users of the communications equipment. Management of RF sources is important for EMI protection of medical equipment that might not be designed for use in proximity to RF communications equipment. This might be particularly true for older medical devices.

5.3.2 Categories of RF communications equipment users

5.3.2.1 General considerations

Users of RF communications equipment can be divided into four categories: staff, non-employee emergency and contract personnel, the general public, and patients. Specific strategies for managing on-site portable and mobile RF sources and for training users are appropriate for each group.

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5.3.2.2 Staff

The staff of a healthcare organization might include physicians; nurses; information technology (IT) professionals; clinical/biomedical engineers; and emergency, security, and maintenance personnel. Staff might need to use a variety of RF communications devices as part of their work and should be trained in EMI risk reduction for each device type. If the staff or general public is allowed to use RF sources within the healthcare facility, it is particularly important that the staff be adequately trained in the recognition and prevention of EMI problems.

Some hospitals require staff members to sign formal statements attesting to their knowledge of EMI risks before they are issued RF communications equipment. Healthcare organizations can establish other appropriate limitations and restrictions on their staff to reduce EMI risk, and the Safety Committee can monitor compliance and act on any deviations from the organization's EMC/EMI policies and procedures.

5.3.2.3 Non-employee emergency and contract personnel

This category of RF communications equipment users includes police officers, fire fighters, ambulance personnel, utility workers, and contractors. To the extent possible, these personnel should be made aware of EMC/EMI issues and the organization's EMC/EMI policies and procedures.

5.3.2.4 General public

The general public includes visitors. Although the general public is somewhat aware of EMI risk factors because of airline travel, it cannot be assumed that they fully understand the issues. Prominently placed signs can be a helpful reminder for visitors but should not be relied on as the sole means to communicate with them. In areas where critical medical devices are used, the staff should be alert to the operation or use of RF transmitters in proximity to electronic medical devices. The staff should also be aware of the possibility of hidden RF sources, such as cellular or PCS telephones carried in jacket pockets or purses. If applicable, the staff should be prepared to explain the difference between communications equipment used by staff members and that used by patients and visitors. Although cellular telephones emit RF even when in the standby mode, the RF energy emitted when the telephone "rings" is of most concern. If a visitor or patient is standing near a medical device when the phone rings, the RF emitted by a cellular telephone could exceed the EMC design specification of the device. Because of this problem, staff should be mindful of possible interference symptoms and be ready to question patients or visitors to determine if hidden RF sources are present. If the staff or general public is allowed to use RF sources within the healthcare facility, it is particularly important that the staff be adequately trained in the recognition and prevention of EMI problems.

5.3.2.5 Patients

Healthcare organizations sometimes permit the use of patient-owned equipment within certain areas of the clinical environment. Such policies should be reviewed to ensure that there are no significant EMI or other risks to medical instrumentation.

5.3.3 Portable and mobile RF source management strategies

5.3.3.1 General considerations

Various strategies could be appropriate for managing the use of on-site portable and mobile RF sources in order to minimize any associated EMI risks. In general, such strategies are aimed at reducing the field strength to which electronic medical devices are exposed by controlling the power of in-house portable RF transmitters or increasing the separation distance between portable RF transmitters and susceptible medical devices. These strategies are applied, as needed, to the user groups.

5.3.3.2 Two-way radios

The highest priority should be the management of the highest-power transmitters in areas where critical medical devices are used. In general, the highest-power portable transmitters are two-way radios, which are used by the following groups:

a) **Staff:** Two-way radios should not be the primary means of communication for the staff of a healthcare organization. Emergency, security, and maintenance staff that use two-way radios should be specially instructed on where and how radio operation could place medical instrumentation at risk. Because of the higher transmitting power of two-way radios, it could be necessary to prohibit such RF transmissions or to increase separation distances in areas where critical medical devices are used. Users of hand-held two-way radios can use them in a receive-only mode (like pagers) and use local telephones or low-power RF wireless equipment to return calls. In general, a distance of at least 3 meters (approximately 10 feet) should be maintained between two-way radios and critical medical devices.

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b) **Non-employee emergency and contract personnel:** Non-employee emergency and contract personnel who use two-way radios should also be specially instructed on where and how radio operation could place medical instrumentation at risk. Because of the higher transmitting power of two-way radios, it could be necessary to prohibit such RF transmissions or to increase separation distances in areas where critical medical devices are used. In general, a distance of at least 3 meters (approximately 10 feet) should be maintained between two-way radios and critical medical devices.

c) **General public and patients:** The general public and patients should not be allowed to use radios in the vicinity of medical equipment unless the immunity of the medical equipment to those radios has been demonstrated.

5.3.3.3 Mobile (cellular and PCS) phones and similar portable wireless equipment

5.3.3.3.1 Balancing the need for communication and EMC

With proper planning and management, staff and patient education, testing (when appropriate), and oversight, appropriate strategies for the use of mobile (cellular and PCS) phones and similar portable wireless equipment can be implemented to balance the need for effective communication and the need to minimize EMI risks.

5.3.3.3.2 Usage restrictions

Restrictions on the use of RF transmitters could be warranted in specific, well-defined clinical areas because of EMI risks to critical medical devices or systems. In such cases, it is recommended that surrounding areas also be evaluated for the need for restrictions on the use of RF transmitters. Concurrently, carefully selected specific areas where RF transmitters are permissible (e.g., visitors' and staff lounges) should be designated so that those wishing to use transmitters can do so without affecting critical medical devices. However, care should be taken that areas where the use of RF transmitters is permitted are not adjacent to critical-care areas where they are prohibited because walls, floors, and ceilings might provide little RF shielding. It should also be ensured that any mobile medical devices that might be moved into areas where RF sources are permitted will not malfunction near such RF sources (e.g., previous ad hoc testing has demonstrated sufficient EM immunity). If the use of RF transmitters is prohibited in certain areas, it is important that users be instructed to power off their communications equipment. In some cases, these restrictions could be necessary for all user groups.

5.3.3.3.3 Total ban of RF wireless technology

Appropriate use of the EMC/EMI management strategies discussed in this TIR will generally make total bans of RF wireless technology unnecessary. However, because of the potential susceptibility of some critical and life-supporting devices and systems, it is recommended that portable communications devices (wireless transmitters such as cellular phones and portable radios) be carefully managed or limited in use around critical medical devices.

5.3.3.3.4 Strategies for low transmission power

At very low RF output power levels (e.g., 10 milliwatts [mW] or less), RF signal strength is generally not high enough to cause EMI in equipment that is not an RF receiver. For example, devices for telemetry transmission of the electrocardiogram (ECG), typically known as wireless medical telemetry devices, have been used for many years with minimal interference caused by the telemetry itself. Wireless communication within the healthcare facility can be achieved with the least risk in several ways:

a) Using in-house wireless communications systems with inherently low power and providing staff with low-power handsets

b) Installing communications network infrastructure to control mobile phone handsets from one or more service providers to transmit at low power

Some communications systems employ "microcell" technology comprising one or more small local telecommunications "cells" with a range that covers only the facility. The base stations and hand-held units are all low-power as compared to what might be achieved when using a cellular phone outside of the healthcare facility. Some microcell "base stations" are in fact distributed antennas consisting of coaxial cable with a "leaky" shield that make the low-level RF available for nearby communications with cellular phones. For this type of equipment, the risk of EMI to medical devices is generally fairly low. The goal is to provide network signal coverage throughout a facility that is sufficient to direct mobile phone handsets to transmit at substantially lower power, particularly in areas where critical medical devices are used.

Transmitters with output power between 10 mW and 100 mW are also less likely to affect medical devices; however, mitigation and/or investigation might be necessary on a case-by-case basis. *RF equipment having output power greater than 100 mW should be evaluated for effects on critical medical devices* (see 6.4). New portable and mobile RF transmitters should also be evaluated in this manner, preferably prior to purchase.

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Full document details: AAMI TIR18:2010, Guidance on electromagnetic compatibility of medical devices in healthcare facilities