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Technical Information Report

AAMI TIR18:1997

Guidance on electromagnetic compatibility of medical devices for clinical/biomedical engineers—
Part 1: Radiated radio-frequency electromagnetic energy

AAMI
Association for the Advancement of Medical Instrumentation

AAMI TIR No.18—1997

Guidance on Electromagnetic Compatibility of Medical Devices for Clinical/Biomedical Engineers—Part 1: Radiated Radio-Frequency Electromagnetic Energy

Approved 4 August 1997

Abstract: This AAMI Technical Information Report (TIR) provides information and guidance to clinical engineers and other biomedical personnel on electromagnetic compatibility (EMC) of medical devices. It is intended to help them evaluate the radiated radio-frequency (RF) electromagnetic environment in their individual health care facilities and implement actions needed to minimize electromagnetic interference (EMI) problems. The TIR covers general recommendations regarding EMC, with emphasis on radiated RF immunity. Principles of electromagnetic energy and interference mechanisms are discussed, as are: assessment of the radiated RF electromagnetic environment; site selection, design, and construction of new facilities; management of the radiated RF electromagnetic environment; management of medical devices for EMC; investigation and reporting of EMI problems; selected case studies in radiated EMI problems; and a model EMC/EMI policy and guidance for developing EMC/EMI policies. Definitions of terms and a bibliography are also provided.

Keywords: ad hoc testing, cellular telephones, conducted, EMC, EMI, ESD, PCS telephones, radiated, RF immunity, wireless LANs

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FOREWORD

The electromagnetic environment in modern health care facilities can be extremely variable, particularly as a result of the tremendous growth in wireless communications. As a result, electromagnetic compatibility (EMC) of medical devices cannot be specified and then forgotten. Health care facilities must actively manage their equipment to assure EMC and mitigate the risks of EMI.

This TIR reflects the conscientious efforts of concerned medical device users, health care professionals, and medical device manufacturers to develop guidelines for control of EMI due to radiated radio-frequency (RF) electromagnetic disturbance (EMD). It was developed by the AAMI EMC 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, such as portable cellular telephones, and what could be done to mitigate those risks. It was inspired in part by Paperman et al. (1994).

The objective of this report is to help clinical engineers and other biomedical personnel assess the radiated electromagnetic environment in their individual health care facilities and implement actions needed to minimize radiated EMI problems and promote EMC. It provides background information on electromagnetic energy and interference mechanisms and discusses what might be done to promote EMC for existing equipment and facilities as well as for new equipment and facilities. It includes several case studies to illustrate the types of EMI problems that can occur. This TIR also provides a model EMC/EMI policy that can be tailored to meet the needs of an individual health care facility.

ACKNOWLEDGMENTS

The Electromagnetic Compatibility Committee gratefully acknowledges the contributions of the following individuals who participated in the development of this Technical Information Report: Joseph Butler, Parker Chomerics; William Kole, Hewlett Packard Company; David Paperman, Texas Childrens Hospital; Mark Pettinato, Walter Reed Army Medical Center; and Donald M. Witters, FDA/CDRH. The committee also recognizes Terry Clemans for developing the first draft of the document, Guy Knickerbocker and Donald M. Witters for developing the first draft of the Model Policy, and David A. Townsend for developing the first draft of annex C.

GUIDANCE ON ELECTROMAGNETIC COMPATIBILITY OF MEDICAL DEVICES FOR CLINICAL/BIOMEDICAL ENGINEERS—PART 1: RADIATED RADIO-FREQUENCY ELECTROMAGNETIC ENERGY

1 Introduction and scope

RF sources have proliferated in health care facilities, creating the potential for EMI with electronic medical devices and with other equipment (e.g., personal pagers, bar code systems, security systems, fire alarm systems, nurse call systems). Many electronic medical devices presently in use have not been tested for immunity to EMD, and some are at risk of failure or malfunction due to interference from portable, mobile, and fixed RF sources both within and outside the health care facility. Numerous EMI incidents have been reported in the literature (e.g., ECRI, 1993a; ECRI, 1993b; Knudson and Bulkeley, 1994; Silberberg, 1993). EMI problems can be expected to occur more frequently with the increasing use in health care environments of electronic medical devices, such as microprocessor-based diagnostic, monitoring, and therapeutic equipment, and portable RF sources, such as two-way radio transmitters and cellular and PCS telephones.

The performance of electronic medical devices can be disrupted by electromagnetic energy 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 ESD. Harmonics imposed on the AC power line by electronic loads (e.g., power supplies) can also cause overheating of power distribution transformers and device power supplies. Because of the high level of interest in wireless communications (e.g., cellular and PCS telephones, wireless LANs) and in order to disseminate relevant information in a timely manner, this TIR focuses on EMI due to radiated RF EMD.

The purpose of this TIR is to help clinical engineers and other biomedical personnel evaluate the radiated electromagnetic environment in their individual health care facilities and implement actions needed to minimize radiated EMI problems and promote EMC. This TIR covers the following topics:

a) general recommendations;
b) principles of electromagnetic energy and interference mechanisms;
c) assessment of the radiated RF electromagnetic environment in existing facilities;
d) site selection, design, and construction of new facilities;
e) management of the radiated RF electromagnetic environment;
f) management of medical devices for EMC;
g) investigation and reporting of EMI problems;
h) selected case studies in radiated EMI problems;
i) a model EMC/EMI policy and guidance for developing EMC/EMI policies.

The TIR also provides definitions of terms and a bibliography for further reference.

2 Abbreviations and definitions

2.1 Abbreviations

ANSI American National Standards Institute

CCU	Critical Care Unit
CT	Computed tomography
CW	Continuous wave
DC	Direct current
EEG	Electroencephalography or electroencephalogram
EMC	Electromagnetic compatibility
EMD	Electromagnetic disturbance
EMG	Electromyography or electromyogram
EMI	Electromagnetic interference
ER	Emergency Room
ESD	Electrostatic discharge
FOI	Freedom of Information
GSM	Global System for Mobile Communications
ICD	Implantable cardioverter defibrillator
ICU	Intensive Care Unit
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
ISO	International Organization for Standardization
LAN	Local area network
MRI	Magnetic resonance imaging
NBICU	New Born Intensive Care Unit
NPF	No problem found
OR	Operating Room
PCA	Patient-controlled analgesic
PCS	Personal communication services
RF	Radio frequency
SMDA	Safe Medical Devices Act

2.2 Definitions[1]

For purposes of this AAMI Technical Information Report, the following definitions apply.

2.2.1 degradation (of performance): An undesired departure in the operational performance of any equipment and/or system from its intended performance.

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

2.2.2 electromagnetic compatibility: The ability of an equipment and/or system to function satisfactorily in its electromagnetic environment without introducing intolerable EMD to anything in that environment.

2.2.3 electromagnetic disturbance: Any electromagnetic phenomenon which may degrade the performance of an equipment and/or system.

NOTE—An EMD may be an electromagnetic noise, an unwanted signal, or a change in the propagation medium itself.

2.2.4 electromagnetic emission: The phenomenon by which electromagnetic energy emanates from a source.

2.2.5 electromagnetic environment: The totality of electromagnetic phenomena existing at a given location.

2.2.6 electromagnetic interference: Degradation of the performance of a piece of equipment, transmission channel, or system caused by an EMD.

2.2.7 electrostatic discharge: A transfer of electric charge between bodies of different electrostatic potential in proximity or through direct contact.

2.2.8 far field: A distance from the antenna of an RF transmitter that is more than several wavelengths of the transmit frequency (refer to section 4.3.1).

2.2.9 immunity: The ability of an equipment and/or system to perform without degradation in the presence of an EMD.

2.2.10 near field: A distance from the antenna of an RF transmitter that is less than several wavelengths of the transmit frequency (refer to section 4.3.1).

2.2.11 radio frequency: A 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 3000 GHz.

2.2.12 susceptibility: The inability of an equipment and/or system to perform without degradation in the presence of an EMD.

[1] All definitions are excerpted from the 1990 IEC publication 60050-161 except 2.2.6, 2.2.8, and 2.2.10-2.2.11. Definitions 2.2.6 and 2.2.11 are excerpted from the 1992 ANSI publication C63.14.

NOTE—Susceptibility is a lack of immunity.

3 Recommendations

At this time, EMC is judged to be of sufficient concern that the actions below are recommended to all health care organizations. Careful consideration of this TIR in its entirety will aid in understanding this important issue.

3.1 Because of their responsibility for the safe functioning of patient care equipment, clinical/biomedical engineers should be the focal point for EMC, EMI mitigation, and EMC/EMI education/training within the health care organization. (See annex A.)

3.2 Purchase, installation, service, and management of all equipment (medical, communications, building systems, and information technology) used in the facility should be coordinated to assure EMC. Clinical/biomedical engineering, facility management, information systems, materials management, and risk management personnel should all be aware of the possibility for equipment interactions and the need for coordination. (See annex A.)

3.3 EMC/EMI should become a permanent responsibility of the health care organization's Safety Committee. (See annex A.)

3.4 Staff, visitors, and patients, including home-care patients, should be educated regarding the nature of EMI and how they can recognize and help prevent it. (See section 8.2.1.)

3.5 EMC should be considered in the site selection, design, construction, and layout of health care facilities. (See section 6 and section 7.3.1.)

3.6 Clinical/biomedical engineers should work with facility management, telecommunications, information systems, materials management, and risk management personnel to manage the electromagnetic environment of the health care facility. (See sections 5 and 7.)

3.7 The institution's administration or its designate, e.g., the Safety Committee, should promulgate policies and procedures that clearly set forth the intentions of the institution regarding management to achieve EMC including, among other things, the designation of areas of the facility where the use of common hand-held RF transmitters (e.g., cellular and PCS telephones, two-way radios) by staff, visitors, and/or patients is to be managed or restricted. (See annex A.)

3.8 Ad hoc radiated RF immunity testing should be considered when EMI is suspected, when RF transmitters are likely to operate in proximity to critical care medical devices, in prepurchase evaluation of new types of RF transmitters to determine their effect on existing medical devices, in prepurchase evaluation of new electronic medical devices, and when checking for age-related changes in medical device RF immunity. Ad hoc testing can be used to estimate the minimum distance that should be maintained between a specific RF transmitter and a specific medical device to mitigate EMI. Policies and procedures for EMI mitigation should be based on objective information, such as that obtainable by ad hoc RF immunity testing. (See section 8.2.3.)

3.9 RF transmitters purchased for use in the facility should have the lowest possible output power rating that can be used to accomplish the intended purpose. (See section 7.1.2.)

3.10 Electrically-powered medical devices purchased for use in the facility should meet EMC standards. (See section 8.1.)

3.11 Electronic medical devices used in intense electromagnetic environments, such as near ambulance radios or in electrosurgery, should have EMC specifications suitable for these environments. (See section 8.1.)

3.12 Clinical/biomedical engineers should consider tracking "NPF" service calls by the location, date, and time of the reported malfunction. This can help associate malfunctions with sources of EMD. (See section 8.2.2.)

3.13 EMI problems should be reported to the manufacturer and to regulatory authorities. (See section 9 and annex A.)

3.14 The health care organization may want to consider obtaining the services of an EMC professional for assistance in characterizing the electromagnetic environment, solving specific problems, and/or educating staff. (See sections 6, 7, and 9, and annex A.)

4 Principles of electromagnetic energy and interference mechanisms

To solve and prevent EMI problems, it is important to understand the physics of the coupling of electromagnetic energy from electromagnetic sources into electronic medical devices and the ways in which this electromagnetic energy can interfere with device function.

4.1 Coupling of electromagnetic energy

Electromagnetic energy is coupled from one piece of equipment to another by radiation, conduction, and/or induction.

4.1.1 Radiation

In coupling by radiation, the energy propagates through space (and through the air) in the form of electromagnetic waves that are "launched" by the source and "received" by a wire or other conductor in the susceptible device. If the source is sufficiently intense and the medical device sufficiently susceptible, they do not need to be in proximity. For example, Ruggera and O'Bryan (1991) reported that apnea monitors detected false breaths when the intensity of ambient FM radio broadcast signals was changed by the movement of people and objects in the vicinity of the monitor.

It should be noted that radiated electromagnetic energy usually must be converted to conducted electromagnetic energy in a wire or component of the susceptible device before it can have an effect.

4.1.2 Conduction

In coupling by conduction, there is a direct electrical path between the electromagnetic source and the susceptible device, i.e., a physical connection between devices. For example, the RF electromagnetic energy generated by an electrosurgical unit can be coupled through a patient to an electrocardiograph or a cardiac monitor. RF and transient electromagnetic energy can also enter through a device's power cord.

4.1.3 Induction

In coupling by induction, there is magnetic or capacitive coupling of electromagnetic energy from the source to a nearby susceptible device. An example of magnetic coupling is the jitter in a CRT display when it is located close to high-current AC power feeder cables in the adjacent wall or floor. Capacitive coupling can occur when long lengths of cable from different devices are routed in parallel.

4.2 Mechanisms of EMI

Electromagnetic interference occurs when an electromagnetic signal intended for another "receiver" is coupled into a susceptible device, is processed with or in place of the intended signal within the device, and causes deviation from normal performance. For example, Paperman et al. (1994) reported EMI with a hospital radio paging receiver that was caused by a bedside monitor. The paging receiver was overloaded by RF emitted unintentionally from the monitor. Silbert et al. (1994) reported artifacts in an EEG caused by cellular telephones. This TIR is concerned primarily with radiated EMI.

Once electromagnetic energy couples to a device's wires or components, it can affect the circuit through the mechanisms of junction rectification, bit corruption, and/or co-channel or adjacent channel interference.

4.2.1 Junction rectification

Junction rectification, or autorectification, occurs when an alternating current is passed through a semiconductor. The nonlinear response of an individual semiconductor junction to current passing through it, in combination with parasitic or intentional circuit capacitance, can result in conversion of a CW RF signal to a DC voltage or in "detection" of the low-frequency modulation (see section 4.3.5) on an RF carrier. The "detected" signal may appear as a DC level shift (e.g., an error in a measured quantity) or an artifact in a waveform or image. The effect can range from subtle to blatant. It can resemble physiological waveforms closely enough to be mistaken for normal or abnormal clinical data, which can affect alarms, diagnosis, and treatment.

4.2.2 Bit corruption

Bit corruption refers to EMI effects in digital logic circuitry. The electromagnetic energy unintentionally coupled into a circuit overcomes the logic noise margin and "flips" one or more bits from logic "0" to logic "1" or vice versa. If not recognized by error detection algorithms, altered bytes can be interpreted as valid data or operational instructions. The effects can include errors in measured or displayed data, change of operational mode, false alarms, failure to alarm, and "lock-up" or "freezing" of displays and/or functions.

4.2.3 Co-channel, adjacent channel, and intermodulation interference

Medical RF devices such as patient telemetry receivers can be affected by RF signals from other transmitters. Some medical telemetry frequencies are used on a secondary basis, sharing with licensed users of those RF frequencies. Thus if a licensed commercial user on the same channel comes in the immediate

vicinity of the health care facility, transmissions by the licensed user could interfere with reception of the patient signal at the telemetry receiver. Radio-frequency signals that are close to the telemetry frequency and are sufficiently intense could also cause loss of reception or unreliable operation. Intermodulation interference occurs when two ambient RF frequencies "mix" in nonlinear components, such as the RF detector circuit of a telemetry receiver, to form sum and difference frequencies. As reported by Carr and Brown (1993), intermodulation interference in a multi-channel telemetry receiver can cause waveforms from one patient to appear on the channel of another patient.

4.3 Factors affecting the degree of EMI

The degree to which an electronic medical device is affected by radiated electromagnetic energy is influenced by the frequency, power, field strength, modulation, and absorption and reflection of the electromagnetic energy, and by the design and maintenance of the medical device.

4.3.1 Frequency and wavelength

The frequency and wavelength of an electromagnetic wave are related by the following equation:

frequency x wavelength = speed of light = 3.0×10^8 meters per second (m/s) (1)

Example solutions of equation 1 appear in table 1.

Table 1—Example solutions of equation 1

Frequency (MHz)	Wavelength (m)
1	300
3	100
10	30
30	10

Frequency (MHz)	Wavelength (m)
100	3
300	1
1,000	0.3
3,000	0.1

The efficiency of coupling of RF energy in both transmission and reception depends on the relationship of the length of the transmitting antenna and the receiving "antenna" to the wavelength. Maximum efficiency is achieved when the antenna length is 1/4 or 3/4 of a wavelength. A wire in a susceptible circuit will "resonate" at the frequencies for which it is 1/4 and 3/4 of a wavelength. However, electromagnetic energy still couples, although with reduced efficiency, to longer and shorter wires.

Radio-frequency electromagnetic energy refers to the frequency range from about 9 kHz to about 3000 GHz; however, common usage does not extend above 100 GHz. See tables 2 and 3 for frequencies of common transmitters.

4.3.2 Radiated power

The radiated power by which a transmitter "launches" an RF wave affects the field strength measured at a given distance from that source. It is a function of the output power of the transmitter and of the antenna

efficiency. Higher power transmitters can affect susceptible medical devices at greater distances. See table 2 for the output power of common portable and mobile transmitters and table 3 for the maximum licensed radiated power of common fixed transmitters.

The output power of most transmitters is fixed and can be found in the product description. However, the output power of cellular and PCS telephones is controlled by the base station. To achieve greater sharing of the available frequency spectrum, a cellular or PCS telephone is instructed by the nearest base station to transmit at the lowest power setting for which an acceptable signal is obtained. Thus, in the absence of absorbing and/or reflecting structures, the radiated power of a cellular or PCS telephone will be lower when it is closer to a base station. Conversely, a cellular or PCS telephone in a shielded room will attempt to contact the base station by transmitting at its maximum power.

Table 2—Typical portable and mobile transmitters, frequencies, output power, and estimated field strength at 1 meter

Product	Frequency (MHz)	Output Power (W)	Estimated Field Strength at 1 m (V/m)
Paging transmitters	49	250	110*
Hand-held transceivers (walkie-talkies)	27,49,145,450	5	15*
State police radio	39	100	40
Biomedical telemetry	174 to 216 460 to 470 512 to 566	$0.8x10^{-6}$ 0.002 $0.1x10^{-6}$	0.006* 0.3* 0.002*
Mobile radios	440 to 470	25	35*
Police/ambulance	400 to 900	10 to 100	22 to 70*
Wireless LANs	912	0.1	2.2
Personal digital assistants	896 to 940	4	14
Radio modems	896 to 901	10	22
Cellular telephones	800 to 900	0.6 to 3	5.4 to 12
Cellular telephones (GSM worldwide)**	890 to 915	0.8 to 8	6 to 20
Licensed PCS	1850 to 1910	0.2	3
Unlicensed PCS	1910 to 1950	0.2	3
CISPR 11/22*** equipment	25 to 1000	$0.04x10^{-6}$	0.0014****

* For these transmitters, 1 m is in the near field. Therefore, these field strength estimates may be very inaccurate.

** Not currently used in North America.

*** Industrial, scientific, and medical (CISPR 11) devices that are not intentional emitters of RF and information technology equipment (CISPR 22), each of which are in compliance with the respective emissions standard.

**** This represents the approximate maximum RF field strength at a distance of 1 m from this equipment.

Table 3—Fixed transmitters, frequencies, maximum licensed radiated power, and estimated field strength at 1 kilometer

Product	Frequency (MHz)	Maximum Licensed Radiated Power (W)	Estimated Field Strength at 1 km (V/m)
Amateur radio	Many bands between 1.8 MHz and 300 GHz	1,500	0.1*
AM radio broadcast	0.535 to 1.705	50,000	0.7*
FM radio broadcast	88 to 108	100,000	0.9
TV channels 2-6	2, 3, 4: 54 to 72 5 & 6: 76 to 88	100,000	0.9
TV channels 7-13	174 to 216	316,000	1.7
TV channels 14-69	470 to 806	5,000,000	6.7

* Field strength may be greater if directional antennas are used.

4.3.3 Field strength

The field strength of a radiated RF wave usually refers to the magnitude of the electric (E) field vector. In the far field (farther away than several wavelengths), the field strength varies as the inverse of the distance and the square root of the output power, as shown in equation 2. Equation 2 is known as the “dipole equation” because it specifies the electric field strength at a distance from an ideal dipole antenna.

$$E = \frac{k\sqrt{P}}{d} \qquad (2)$$

In this equation, P is the radiated power in watts (W), d is the distance in meters (m), E is the electric field strength in volts per meter (V/m), and k is a constant in the range of 0.45 to 7, depending on the antenna efficiency of the transmitter. It is not unusual for the actual measured field strength to deviate by a factor of 10 to 100 from this prediction, due to absorption and reflection, as well as the antenna pattern of the transmitter.

See table 2 for estimated field strength at a distance of 1 m from common portable and mobile transmitters and table 3 for estimated field strength at a distance of 1 kilometer (km) from common fixed transmitters. The field strength estimates in table 2 were calculated using k = 7, and the field strength estimates in table 3 were calculated using k = 3.

In free space and in the far field, the magnitude of the magnetic (H) field vector can be determined according to equation 3:

$$H = \frac{E}{377\Omega} \qquad (3)$$

In this equation, E is the electric field strength in V/m, 377Ω is the intrinsic impedance of free space, and H is the magnetic field strength in amperes per meter (A/m).

To estimate the distance from a transmitter at which a particular value of electric field strength would occur, equation 2 can be solved for the distance as follows:

$$d = \frac{k\sqrt{P}}{E} \qquad (4)$$

Example solutions to equation 4 appear in table 4 for several values of radiated power when k = 7 (i.e., worst case, for a transmitter with an antenna length that is 1/4 of the transmit frequency wavelength) and E = 3 V/m (the general radiated RF immunity test level specified in IEC 60601-1-2 [1993]).

Table 4—Example solutions to equation 4 for k = 7 and E = 3 V/m

Radiated Power of Transmitter (W)	Estimated Distance at Which E = 3 V/m (m)
0.01	0.2
0.1	0.7
0.6	2
2	3
5	5
10	7
20	10
50	16
100	23

4.3.4 Absorption and reflection

Due to absorption and/or reflection, the field strength of a radiated electromagnetic wave measured at a point in space can be higher or lower than that predicted by the dipole equation. Conductive surfaces, particularly metallic structures, reflect electromagnetic waves. Materials such as ferrites, and even the bodies of humans and animals, can absorb as well as reflect electromagnetic energy.

Shielding is often used to reduce the field strength in a particular area, such as within the interior of a cable, a medical device, or a room. It accomplishes this by reflecting a large percentage of incident electromagnetic waves. Architectural structures such as aluminum siding or concrete with steel reinforcement can provide a degree of shielding. However, reflection from metallic structures can also cause electromagnetic waves to interfere constructively, such that the field strength at a particular point in space is higher than that predicted by the dipole equation.

4.3.5 Modulation

Radio-frequency signals are seldom transmitted CW. They are usually modulated by a lower frequency waveform, causing the RF to vary in amplitude, frequency, phase, and/or in the form of pulses. The modulation contains the information being transmitted to the intended receiver of the electromagnetic

energy. The modulation is often what is “detected” unintentionally by sensors and/or semiconductor junctions in a susceptible medical device.

4.3.6 Device design

In general, an electronic medical device will be more immune to EMD if it has been designed with EMC in mind. Techniques used by medical device manufacturers to improve immunity to radiated RF EMD include, but are not limited to, shielding, filtering, and the use of ferrite absorbers. For more information on device design techniques, see Kimmel and Gerke, 1995.

4.3.7 Device maintenance

Proper maintenance of electrically-powered equipment is essential to mitigation of EMI. See section 8.2.2.

5 Assessment of the radiated RF electromagnetic environment in existing facilities

To control EMI, it is essential to assess the electromagnetic environment. Radio-frequency sources within and outside the facility should be identified, as well as the areas within the health care facility where patients could be most adversely affected by EMI. Clinical/Biomedical Engineering 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. In assessing the electromagnetic environment, it may be advisable to seek the assistance of EMC professionals.

5.1 Identification of RF sources

The clinical/biomedical engineering staff should identify the RF sources most likely to influence electronic medical devices within the health care facility. An RF survey meter can be used to determine the field strength of identified sources. If RF measurements are made, the frequency, field strength, date, time, and location should be recorded. Radio-frequency sources can be categorized as intentional or unintentional.

5.1.1 Intentional sources

Intentional RF sources use RF energy for communications, control, or for treatment of material or patients and can be categorized as follows:

a) on-site portable and mobile RF sources (e.g., hand-held transceivers [walkie-talkies], cellular and PCS telephones, pharmaceutical robots, RF identification tags, wireless LANs, medical telemetry transmitters);
b) on-site fixed RF sources (e.g., paging transmitters, repeaters for land mobile communications, cellular and PCS base stations);
c) outside portable and mobile RF sources likely to be in the vicinity (e.g., two-way radios in ambulances, police and fire vehicles, taxis, shuttle buses);
d) outside fixed RF sources (e.g., pager transmitters, cellular and PCS base stations, radio and television broadcast transmitters).

A list of RF sources in each of these categories should be established and updated as new communications equipment is brought into service. These lists will be helpful in researching any problems that may be related to EMI.

5.1.2 Unintentional sources

Unintentional RF sources include electrically-powered equipment, even equipment that is battery-powered, that produce RF energy as a by-product of their normal operation. Unintentional RF sources include computers; electronic games; radio and television receivers; fluorescent lamp ballasts; high voltage relays; elevator motors, relays, cables, and controls; and medical imaging systems. Disturbances can be particularly intense in proximity to equipment that generates or uses high voltages or currents.

5.2 Identification of areas where critical medical devices are used

Areas where critical medical devices are used should be identified to aid EMI risk assessment. Clinical/Biomedical Engineering should work with the Safety Committee to ensure that all such areas are identified, and this list should be reviewed periodically. Examples of areas where critical devices are used include ICUs, CCUs, ORs, newborn nurseries and intensive care facilities, labor and delivery rooms, pediatric ICUs, ERs, diagnostic areas such as EEG and EMG units, imaging units, and clinical/diagnostic laboratories.

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

5.3 Ambient electromagnetic measurements

Measurements of the ambient electromagnetic spectrum should be considered for areas where critical devices are used in order to determine the existing frequencies and intensities of electromagnetic radiation within those areas. Such data 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 health care, see annex C.

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, this does not guarantee the absence of EMI problems. Ambient electromagnetic measurements are most useful in characterizing RF fields due to outside fixed sources and in identifying recurring interference problems.

While simple field strength meters are inexpensive, they provide a limited amount of information and they are considerably less accurate than spectrum analyzers. Spectrum analyzers provide more complete and accurate information on frequencies and field strengths; however, they are expensive. Alternatives to purchase of a spectrum analyzer by a health care organization include rental and pooling resources with other organizations.

Environmental site surveys should be conducted in accordance with IEEE 473 (1985), particularly section 5.3, “Interior Locations.”

6 Site selection, design, and construction of new facilities

The location of a health care facility with respect to nearby broadcast transmitters and the physical construction and layout of the facility affect the electromagnetic environment of the medical devices used within the facility. When selecting a site for a new health care facility, electromagnetic spectral measurements should be made at the prospective site to determine the frequencies and field strengths of existing transmitters. If measured field strengths are approximately 3 V/m (the general radiated immunity test level specified by IEC [1993]) or higher, architectural shielding could be required, or perhaps another site should be considered. However, all new facilities should be designed and constructed with EMC in mind. For more information on architectural shielding materials and techniques, see Soltis (1993). See also section 7.3.1.

While not the subject of this report, proper power distribution is also important for device EMC. Power distribution should be designed to minimize conducted interference between high-power equipment (e.g., elevators, medical imaging systems) and low-power equipment (e.g., patient monitors). See IEC 61000-5-2 (1997).

When designing a new health care facility, organizations should consider consulting an EMC professional who is familiar with building design and construction.

7 Management of the radiated RF electromagnetic environment

Effective management of the radiated RF electromagnetic environment is crucial to the prevention of EMI problems and requires control of RF sources, to the extent possible, both within and outside the health care facility. A model policy which may be useful in the management of the radiated RF electromagnetic environment appears in annex A.

7.1 On-site portable and mobile RF sources

In many cases, older medical instrumentation was not designed for use in proximity to modern RF communications equipment. As older medical devices are replaced with newer technology that meets EMC standards, the EMI risk will diminish. In the meantime, limitations on the use of RF transmitters may be necessary. Based on the identified RF sources and areas where critical medical devices are used, strategies can be formulated to manage the use of RF communications equipment.

7.1.1 Categories of RF communications equipment users

Users of RF communications equipment can be divided into three categories: staff and emergency/security personnel, the general public, and patients.

Staff and emergency/security personnel: The staff of the health care organization, which includes physicians, nurses, and other employees, should be trained in EMI risk reduction. Emergency and security personnel and maintenance staff who use hand-held transceivers should be instructed on where and how

radio operation can place medical instrumentation at risk. It may be necessary to prohibit RF transmissions in areas where critical medical devices are used, such as ICUs and ERs. Users of hand-held transceivers can operate in a receive-only mode and use local telephones to substitute for the return communication link. Some hospitals require staff to sign formal statements attesting to their knowledge of EMI risks before the staff are issued RF communications equipment. Health care 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.

General public: Visitors and other members of the general public cannot be assumed to be aware of EMI risk factors. Prominently placed signs can be helpful, as well as announcements on the public address system (e.g., for visually impaired visitors). However, the staff of the health care organization must provide the primary safety net in reducing EMI risk. 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. Cellular and PCS telephones emit RF even when in the standby mode. If a visitor or patient is standing near a ventilator, infusion pump, or infant incubator, the RF emitted by a cellular telephone can easily exceed the EMC design specification of the medical device. Because of this problem, staff should be mindful of possible interference symptoms and be ready to question the general public to determine if hidden RF sources are present. If the general public is allowed to use RF sources within the health care facility, it is particularly important that the staff be adequately trained in the recognition and prevention of EMI problems.

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

7.1.2 Management strategies

Various strategies are being employed to manage the use of on-site portable and mobile RF sources in order to minimize any associated EMI risks. In general, they strive to reduce the field strength to which electronic medical devices are exposed by increasing the separation distance between portable RF transmitters and susceptible medical devices. Otherwise, RF transmitters could be brought to within inches of medical devices. As the distance approaches zero, the high field strength which occurs very close to the antenna of an RF transmitter can cause unpredictable performance problems in medical devices not specifically designed for use in intense RF environments. These strategies are applied, as needed, to the three user groups. Because RF source management policies are difficult to enforce, it is important that users be educated and/or informed of the possible consequences of EMI and the importance of adhering to the organization's policies and procedures. This will improve voluntary compliance. Signs announcing the policies and procedures should be prominently displayed, and informational brochures explaining the rationale and details of the policies and procedures should be placed close to the signs. The information should also be available in a form that is accessible to the visually impaired. If the use of RF transmitters is prohibited in certain areas, it is important to offer communications alternatives for each of the user groups. Policies and procedures regarding the use of RF transmitters should be based on objective information, including the characteristics of the RF sources in and around the facility and the estimated susceptibility of the organization's medical devices (see section 8).

Partial restriction: If those areas where critical medical devices are used have been clearly defined, RF transmitters can be prohibited in and around those areas and permitted in other areas, e.g., visitor's lounges. However, care should be taken that areas where the use of RF transmitters is permitted and areas where it is prohibited are not separated by only a wall, floor or ceiling, because these structures generally provide little RF shielding.

Total ban: When RF transmitters pose uncontrollable risks to medical instrumentation, a total ban of particular types of RF communications equipment can be instituted. Examples of situations in which a total ban may be appropriate include the following:

a) Waiting rooms or other public areas are located near areas where critical medical devices are used, and the use of RF communications equipment may violate the EMC specifications of particular medical devices.

b) Specific medical devices have extremely low immunity to radiated RF EMD, and device failure or malfunction could result in the serious injury or death of patients.

RF Technology: Some RF sources transmit at low power levels (e.g., 10 mW or less) in order to conserve batteries, decrease weight, or increase portability. At such low power levels, the signal strength is generally not high enough to cause EMI. For example, devices for telemetry transmission of the electrocardiogram (ECG) have been used for many years and have caused minimal interference with other medical devices. Some of the new communications systems employ microcell technology. Microcell systems comprise a very small local telecommunications "cell" with a range that covers only the facility. The base stations and hand-held units are all very low power. Some microcell "base stations" are in fact distributed antennas consisting of coaxial cable with a "leaky" shield. For this type of equipment, no action may be necessary to prevent EMI risks. Transmitters with output power between 10 mW and 100 mW are unlikely to affect medical devices; however, mitigation and/or investigation may be necessary on a case-by-case basis. RF equipment used within the facility having output power greater than 100 mW should be evaluated for effects on critical medical devices (see section 8.2.3). New portable and mobile RF transmitters (e.g., portable base stations, two-way radios, wireless computer equipment, cellular and PCS systems) should also be evaluated in this manner, preferably prior to purchase.

7.2 On-site fixed RF sources

On-site fixed RF sources include pager transmitters, commercial and safety service RF repeaters, and cellular and PCS base stations.

7.2.1 Pager transmitters

Pager transmitters, which transmit at power levels in the range of 150 to 300 W, should not be located in proximity to medical instrumentation. The safe distance depends on the frequency, power, and especially the radiation pattern of the antenna. Analysis will help determine the EMI risk (see section 7.2.4). Some health care organizations permit high-power transmitters to operate within their facility to improve coverage in areas where reception would otherwise be difficult. This type of installation should be closely reviewed.

7.2.2 Commercial and safety service RF repeaters and cellular and PCS base stations

It is not unusual for hospitals to rent roof space to commercial communications services and to police, fire, and transportation departments for remote radio repeaters, or to cellular and PCS telephone companies for base stations. The radio repeaters receive signals from local portable and mobile sources and retransmit them at higher power to remote receivers. Cellular and PCS base stations typically handle communications with the hand-held units that are in the cell and connect them to the wired, land-based telephone network. In some cases, it is preferred that the health care organization provide roof space so that such outside transmitters are not located across the street on lower buildings and radiate even higher field strengths into the hospital. Care should be taken not to locate RF repeaters too close to medical instrumentation, particularly in areas such as nurseries, ECG telemetry facilities, and EEG units. The appropriate distance can be estimated from the analysis described in section 7.2.4. Health care organizations are encouraged to characterize (frequency, power, and radiation pattern) all privately owned transmitters located on the premises. See table 5 and figure 1 for an example.

Table 5—Rooftop transmitters at a hospital

Reference (Figure 1)	Type of Service	Location	Frequency (MHz)	Output Power (W)	Effective Radiated Power* (W)
(A)	Cellular telephone repeater	9th floor	806 to 960	10	
(B)	Long range paging system repeater	9th floor	929.6125 929.5625 929.7375	300	1000
(C)	Long range paging system repeater	9th floor	929.5875 929.9375 929.4125 929.4625 929.6375 929.5125 929.8625 929.6875	250	1000
(D) (E) (F)	Long range paging system repeater	9th floor 9th floor	931.8625 454.2750 929.1375	189 182	1000 500
 (G) (H)	Local school system: repeater for bus transportation repeater for school maintenance	 9th floor 9th floor	 463.6500 463.3250	 75 75	
	Two-way radio transmitter for in-house security	5th floor	461.4500	25	95
	In-house transmitter for short range paging system	5th floor	462.9500	35	35

***** Factors such as antenna gain and filters affect the effective radiated power.

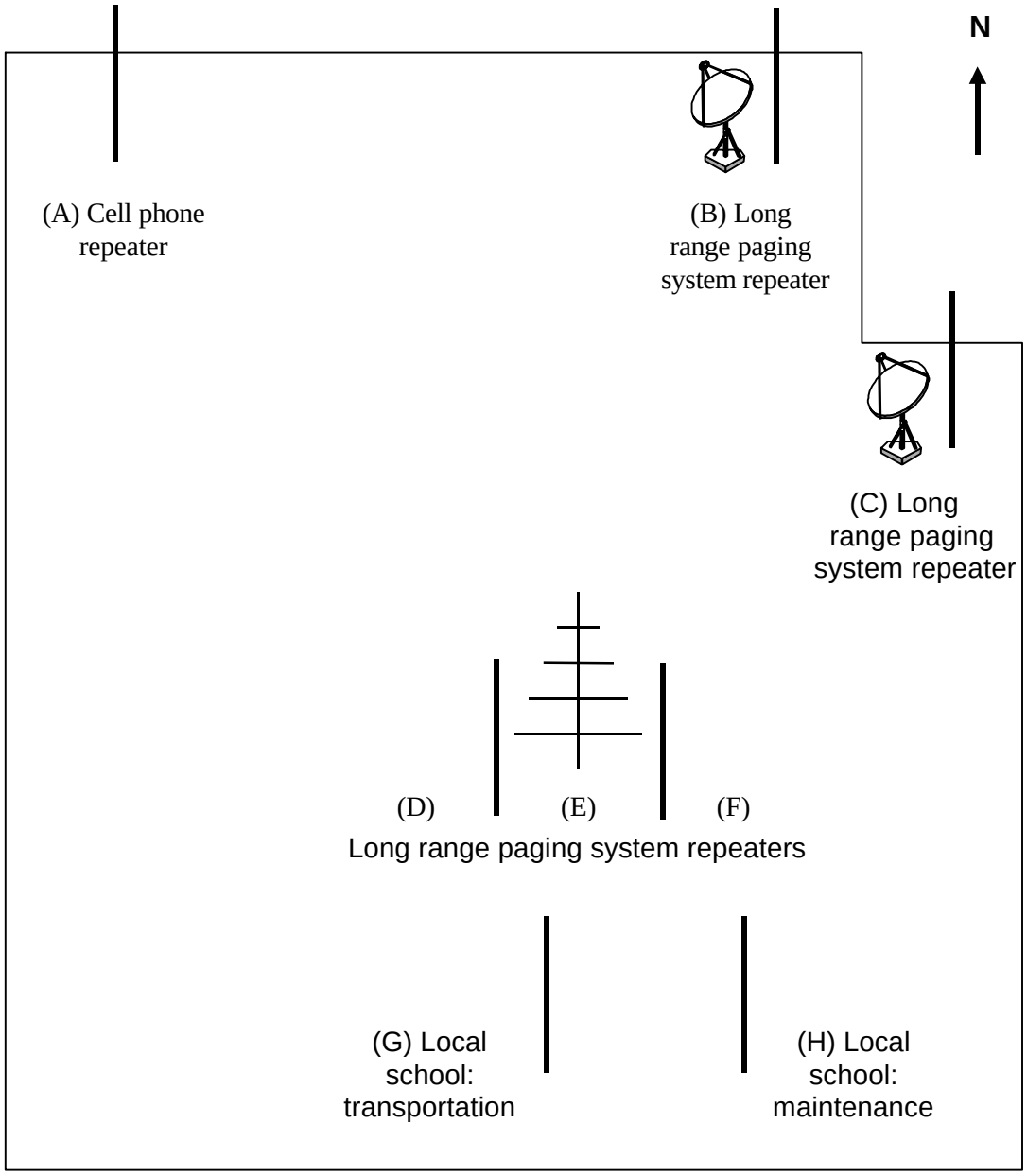

Figure 1 —Arrangement of antennas on 9th floor roof of a hospital

7.2.3 Outside RF sources

Outside RF sources may be portable, mobile, or fixed. Power and other utility companies occasionally use portable two-way radios in the vicinity of health care facilities. Outside mobile RF sources include police and fire department vehicles, ambulances, and publicly or privately owned vehicles containing radio transceivers. Many health care facilities have architectural features that permit vehicles to be driven next to, under, or over areas where critical medical devices are used. Some health care facilities are located near high-power fixed RF transmission sources, such as pager transmitters and radio and television broadcast transmitters.

Outside RF sources should be individually assessed according to such parameters as power level, radiation pattern, modulation type, and distance. Portable and mobile RF sources can, of course, be somewhat unpredictable, whereas fixed RF sources can have relatively consistent effects. Many factors influence the RF field strength at the location of a medical device; consequently, it is advisable to make actual measurements, as described in section 5. If outside portable and/or mobile RF transmitters are found to be a significant source of EMI problems, notices can be posted outside the facility asking users of portable and/or mobile radios to avoid transmitting in the immediate vicinity of the facility.

Outside fixed RF sources can affect electronic medical devices inside of the facility, particularly those that are directly adjacent to outside walls. Also, a wide range of RF frequencies can pass readily through glass windows, depending on the reflection/glare reduction material used (if any) and the adequacy of the bonding (if any) between the reflection/glare reduction material, the window frame, and earth ground. EMI problems from outside fixed RF sources can sometimes be solved by moving a particular medical device to a different location within a room or to a different location within the health care facility.

7.2.4 Analysis

Using the information gathered from the listing of RF sources, an analysis can be performed to estimate RF field strengths from outside sources. Since there are so many variables, a worst-case analysis is appropriate. Radiation patterns, the effects of reflection of RF signals from outside buildings, and changes in RF signals caused by inside building architecture (see Soltis, 1993) are all parameters that are difficult to assess on paper. However, a theoretical analysis can determine the likelihood that the RF field strength will be high enough to exceed the EMC specifications of medical equipment. If the calculations suggest that EMI may be a problem, an RF measurement survey can be performed in areas where critical medical devices are used. An EMC professional may be able to provide assistance in this area. (See section 5.3.)

7.3 Other EMI mitigation measures

After RF source information is accumulated to properly assess areas that are at high risk for EMI, corrective actions can be taken. Solutions may include: relocating high-risk departments to different areas within the health care facility (see section 7.3.1); installing RF shielding in areas where sensitive medical devices are used (see NOTE, in section 7.3.1); updating older devices with newer, EMI-immune technology; working with vendors to improve EMC specifications for existing devices; and instructing staff in the areas where critical medical devices are used on how to recognize EMI problems. (See also section 8.)

7.3.1 Floorplanning

Floorplanning is important for both new and existing facilities. Units in which particularly sensitive devices are used, such as fetal heart monitors, EEG equipment, EMG equipment, and older apnea monitors, should not be located near areas where intense RF emissions can occur, including emissions from electrosurgical suites and from unintentional sources such as imaging systems and elevators. Attention should also be paid to equipment located on the floor above and below sensitive medical devices, as well as proximity to rooftop transmitters and outside walls or drive-throughs that might be exposed to portable or mobile two-way radios at close range. In some existing facilities, certain rooms may need to be shielded to assure proper operation of susceptible medical devices in those rooms.

NOTE—If RF shielding is installed in certain areas, RF propagation patterns are affected both inside and outside the shielded area. Unless RF-absorbing material is used, portable transmitters may need to be used with caution in or prohibited from shielded areas (see Liu-Hinz et al., 1996).

8 Management of medical devices for EMC

The electromagnetic emissions and susceptibility of medical devices vary. Potential EMI problems can be prevented through prepurchase evaluation of new devices and proper evaluation and maintenance of existing devices. In some cases, upgrade or replacement of existing devices may be appropriate.

8.1 New medical devices

Manufacturers should be requested to provide EMC specifications and/or information on device-related EMI incidents reported by users of the electrically-powered medical devices being considered for purchase. Medical device EMC specifications should be evaluated based on the electromagnetic environment in which the device is expected to be used. IEC 60601-1-2 (1993) specifies general EMC requirements for medical electrical equipment. Compliance with this standard is recommended as a minimum, and this may be sufficient for devices used in areas where the field strengths are less than 3 V/m. For devices used in intense electromagnetic environments, such as electrosurgery or areas near ambulance radios, higher EMI immunity may be necessary.

Some device specific standards published by ISO and IEC (e.g., the IEC 60601-2 series) may also include EMC requirements, and these can modify the general EMC standard. Information on any of these standards is available form AAMI.

Manufacturers' summary EMC test results should be examined for the claimed level of electromagnetic immunity, the effects of the test signal(s), if any, and the characteristics of the test signals(s) (e.g., frequency, modulation, field strength to which the device was exposed) at which these effects were observed. Manufacturers' EMC testing is performed only on a small number of units. The results will be indicative of the general EMC properties of a given model; however, variation in individual device EMC properties may occur. Also, the EMC test signal(s) may be somewhat different from the RF sources used in the health care facility. Therefore, ad hoc EMC testing of individual electronic medical devices purchased by the facility should be considered. (See section 8.2.3.)

8.2 Existing medical devices

Many electronic medical devices now in the inventory of health care organizations were not designed or tested for EMC. Some of this equipment can be very susceptible to EMI, with RF immunity as low as 0.1 V/m. These devices can be affected at up to 30 times the distance from an RF transmitter as a device that is immune to 3 V/m. Due to cost constraints, some of this equipment will remain in service for many years. As a consequence, special precautions must be taken to assure EMC of existing equipment, including user training, care in service/maintenance, and ad hoc RF immunity testing.

8.2.1 User training

The medical staff should be informed of the possible symptoms of, and ways to recognize, EMI. Otherwise, it will be very difficult to detect and solve EMI problems in the clinical environment. The same information is essential for home-care users. Training should be provided in recognizing EMI in the home-care environment, with emphasis on the particular electronic medical devices prescribed.

8.2.2 Service/maintenance

It is critically important to reinstall and/or maintain the integrity of EMI mitigation techniques such as shielding and filtering while servicing electrical and electronic medical devices. For example, shields, bonds, ground wires, and cabinet screws should be returned to their original location and condition. Metallic surfaces intentionally left bare for continuity of the shield should not be painted over. A missing cover, screw, ferrite bead, or conductive strap can make a device more susceptible to EMI. It is not common practice to EMC-test devices after repair, so errors in replacement of EMC components may be difficult to detect. Attention should also be paid to cleaning the contacts of connectors, as the semiconductor nature of oxidized contacts may play a role in a possible increase in EMI susceptibility as electronic equipment ages.

NOTE—Only nonabrasive spray cleaners (e.g., “tuner cleaner”) should be used. The device manufacturer’s service instructions should be followed, and the manufacturer should be contacted if there is a problem or question, particularly with regard to shielding and/or EMI gasketing (e.g., broken gasket fingers, missing gasketing, corrosion on surfaces intended to provide continuity of shielding).

EMI might be a possible explanation for device malfunction when problems appear to have self-resolved or cannot be reproduced, particularly after the device has been removed from the environment in which it malfunctioned. EMI is difficult to investigate because the interference may be intermittent, the source may no longer be present, the interference may only occur at a particular time in the operating cycle of the device, or the medical device may be malfunctioning “silently” without triggering any alarms (Segal et al., 1994). As a result, an EMC failure may not be detected the first time a problem is reported.

EMI can be one cause of medical device malfunctions that produce “NPF” service calls, in which a device that has malfunctioned is sent for service and the problem cannot be duplicated by clinical/biomedical engineering staff or a service provider. While probable causes for “NPF” service calls include intermittent hardware problems, software “bugs,” and user error, EMI should be investigated as a possibility. Maintaining a database of such malfunctions by the time, date, and location of occurrence can help identify malfunctions that result from continuous and periodic RF transmissions.

For example, during an EMI risk assessment at the Walter Reed Army Medical Center, two EMI problems were identified by tracking "NPFs." A patient monitoring central station was found to "lock up" periodically during testing of the emergency generator. Also, patient monitors experienced intermittent malfunctions more often on one particular side of one particular floor, which was located above a loading dock. CB or other mobile radio transmissions from vehicles arriving at the loading dock were strongly suspected to have been the cause of the patient monitor interference.

8.2.3 Ad hoc RF immunity testing

It is not practical to perform a thorough assessment of the RF immunity of every electronic medical device in the inventory of a health care organization. Thorough RF immunity testing requires specialized facilities, equipment, and expertise. Equipping and training (or staffing) a clinical/biomedical department to be able to perform such testing would be prohibitively expensive and would be an inappropriate use of resources. Contracting with an EMC laboratory for thorough RF immunity testing of every electronic medical device in a health care organization's inventory would also be prohibitively expensive.

The RF immunity of medical devices to specific RF transmitters can be estimated relatively quickly and inexpensively, however, by performing ad hoc RF immunity testing. To promote consistency of testing and comparability of test results, ANSI-accredited standards committee (ASC) C63 has developed a recommended practice for ad hoc RF immunity testing (ANSI C63.18 [1997], Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Radiated Electromagnetic Immunity of Medical Devices to Specific Radio-Frequency Transmitters). This document is a worthy addition to a health care organization's clinical/biomedical engineering reference library. It can be used to estimate the minimum distance that should be maintained between a specific RF transmitter and a specific medical device to mitigate EMI. Policies and procedures for EMI mitigation should be based on objective information, such as that which can be obtained by the use of this test method.

ANSI C63.18 describes the ad hoc test method itself and also provides guidance in selecting medical devices for RF immunity testing (see below), selecting RF transmitters to use as RF test sources, and interpreting and reporting the test results. It also provides a realistic assessment of the limitations of the test method.

Ad hoc RF immunity testing should be considered when EMI is suspected, when RF transmitters and critical-care medical devices are likely to operate in proximity, in pre-purchase evaluation of new types of RF transmitters to determine their effect on existing medical devices, in pre-purchase evaluation of new electronic medical devices, and when checking for age-related changes in medical device RF immunity.

ANSI C63.18 provides the following guidance for selection of medical devices for ad hoc testing:

> Health care organizations should use their judgment in prioritizing medical devices for ad hoc electromagnetic immunity testing. However, the following factors should be considered:
>
> - the criticality of the medical device (whether it is life-supporting, used to monitor critical patient parameters, provides a diagnosis, delivers drugs);
> - whether the medical device has been tested for compliance with applicable EMC standards;
> - the potential impact of medical device failure or malfunction on the patient (e.g., whether there is potential for patient injury or death);

- known EMI problems with similar medical devices due to insufficient RF immunity;
- whether the medical device contains sensitive components or circuitry (e.g., circuits with high-gain amplifiers, patient leads, and microprocessors can be particularly sensitive);
- whether RF transmitters are frequently used in the vicinity of the medical device (e.g., in ERs);
- whether the medical device has been noted to perform erratically;
- whether the medical device is repeatedly referred for service, yet when the performance of the medical device is tested, no problem is found, particularly when tested in a service location that may be elsewhere in the building (e.g., the basement) or off-site.

See annex A of this TIR for more guidance on ad hoc RF immunity testing and the use of the ANSI C63.18 recommended practice.

8.3 Implantable medical devices

While they are usually more immune to EMD than other devices, implantable electronic medical devices can be affected by RF transmitters at close distances. Barbaro et al. (1995), Carrillo et al. (1995), Hayes et al. (1996), Joyner et al. (1994), and Ruggera and Witters (1996) reported on the effects of cellular telephones on implantable and/or implanted pacemakers. Effects that have been identified from cellular telephones at close range include inhibition, reversion to fixed-rate pacing, and pacing at the programmed high-rate limit. Present industry recommendations are that cellular telephones be kept at least 6 inches away from the pacemaker, that the pacemaker patient use the cellular telephone at the ear opposite the pacemaker, and that pacemaker patients not place a cellular telephone with the power ON in a shirt or jacket pocket that is directly over the pacemaker.

Bassen et al. (1995) reported in vitro findings of two effects on ICDs as a result of digital cellular telephones at distances in the range 2.3 to 5.8 cm: inhibition of the ICD's pacemaker function and unintended discharge.

9 Investigation and reporting of EMI problems

9.1 Investigation

Problem investigations should include assessment of the electromagnetic environment of use and the performance of the device in that environment. If a high field strength signal is identified, ad hoc RF immunity testing should be performed at that frequency, if possible. A malfunction that occurs only in a particular location or appears to correlate with movement of people or objects could be indicative of EMI. Tracking of repeated "NPF" service calls can also help identify EMI problems (see section 8). However, unless the RF transmission is continuous or periodic, it may not be possible to attribute a particular malfunction to EMI. The assistance of EMC professionals, medical device manufacturers, communications equipment manufacturers, and amateur radio operators may be helpful in identifying and solving EMI problems. (See also section 10.)

If a medical device was involved in an incident and may be subject to further investigation to determine its role in that incident, it should not be exposed to field strengths that could damage the device because it is important that such devices not be altered before the investigation is completed. Therefore, it is particularly important that ad hoc radiated RF immunity testing not be performed at distances closer than the minimum

recommended test distance specified in ANSI C63.18 (ANSI, 1997) as appropriate for the output power of the RF transmitter.

9.2 Reporting

EMI problems should be reported to the manufacturer and to regulatory authorities. The SMDA of 1990 requires hospitals and other user facilities to report deaths and serious illnesses and injuries associated with the use of medical devices. EMI problem reporting should be consistent with the health care organization's problem-reporting policies and procedures.

Even if an EMI problem does not meet the requirements for mandatory reporting under the SMDA, it would be helpful to submit a report to MedWatch, the FDA's voluntary reporting program. These reports can be submitted to MedWatch by telephone at 1-800-FDA-1088, by FAX at 1-800-FDA-0178, or by mail to MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20857. Further information on the MedWatch program can also be obtained over the World Wide Web, at http://www.fda.gov/medwatch.

The identity of problem reporters participating in the MedWatch program is protected by the Privacy Act, and is not releasable under the FOI Act. Therefore, reporting a medical device problem to the FDA should not expose the reporter to any additional risk of liability or litigation.

Problem reports that have been submitted to the FDA are generally not obtainable in their entirety because they contain proprietary and privacy-protected information. However, for a particular product or model, "purged" or "redacted" versions of FDA problem reports, from which proprietary and privacy-protected information have been removed, can be accessed by submitting a written request to FDA's FOI Staff, HFI-35, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. The FDA also supplies monthly database updates in the form of magnetic tapes to the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161, and to ECRI, 5200 Butler Pike, Plymouth Meeting, PA 19462. In addition, "purged" or "redacted" versions of CDRH medical device problem reports are available on the World Wide Web and can be accessed from the CDRH home page, http://www.fda.gov/cdrh, by selecting "Program Areas", then "Medical Device Reporting," then "MDR Data File." As of October 1997, the MDR database could be downloaded in one-year increments; however, the files are large and difficult to use. Downloaded files are in ZIP format and range in size up to 8.6 MB. When expanded, the files are "flat" ASCII text files and range in size up to 61 MB. Improved access is being developed and users will eventually be able to search the database on-line, using criteria such as manufacturer and model number, and print and/or download only the reports of interest.

10 Selected case studies in radiated EMI problems

Numerous EMI incidents have been reported in the literature (e.g., ECRI, 1993a, 1993b; Knudson and Bulkeley, 1994; Silberberg, 1993). The selected case studies presented in this section illustrate some of the principles of EMC discussed earlier, as well as approaches to detecting and solving radiated EMI problems. This selection is not intended to be all-inclusive. There are many other possible sources of EMD and effects of EMI.

10.1 EEG equipment

10.1.1 Interference from cellular telephones

Silbert et al. (1994) reported an incident in which cellular telephones caused artifacts in an electroencephalogram. A child was referred to the Mayo Clinic EEG laboratory for evaluation of seizures. The EEG was recorded on a 16-channel Grass electroencephalograph, using collodion electrode application, a 70-Hz low-pass filter, a 1-Hz high-pass filter, and a paper speed of 30 mm/sec. The parents of the boy were present during the procedure. A recurring artifact was seen in the recording and found to have been caused by cellular telephones carried by the parents. The telephones were turned on but not in use (i.e., they were in the standby mode). When the telephones were moved about 20 feet away, the EEG artifacts disappeared.

Further evaluation by the authors of the report revealed that cellular telephones could produce three patterns of EEG artifact, one of which resembled cerebral discharges. As had been seen in the clinical case, it was found experimentally that cellular telephones could generate artifact merely from being turned on, not just when in use. The authors noted that "the experienced technologist and electroencephalographer can clearly identify most of the induced activity as artifactual because of the characteristic morphology and nonphysiological distribution. . . . Recognizing the possibility of a cellular telephone's being responsible for the activity, however, can reduce the time involved in the search for other causes of external interference."

10.1.2 Interference from an elevator relay switching system

A newly opened pediatric ICU was plagued with intermittent interference with an infant ventilator and EEG equipment. The EEG became unusable with erratic tracings, and the ventilator went into alarm. Testing of an old elevator relay switching system yielded probable cause, but subsequent testing failed to produce repeatable results.

10.2 Dialysis equipment

In 1994, an incident occurred in which an FM transmitter interfered with a dialysis machine. During operation of the dialysis machine, it was noted that the loss-of-weight measurement was inaccurate. Further investigation revealed that a nearby FM radio transmitter had caused interference with the measurement circuitry of the dialysis machine. The manufacturer of the dialysis machine recommended using EMC paint on the inside of the plastic outer case to reduce RF penetration. New units in production now have EMC paint as a standard feature.

10.3 Ventilators

10.3.1 Interference from a two-way radio

At a Midwest hospital in 1993, a mobile business band radio caused false alarms in infant ventilators. A group of ventilators located in a ground-floor ICU alarmed simultaneously when a hospital-owned bus was being driven next to the hospital building and a two-way radio was being operated. Testing during investigation of the incident showed that the ventilators were also sensitive to hand-held transceivers, particularly when the ventilators were being operated in the pediatric/infant mode. The actions taken were to restrict the use of mobile vehicle radios near the building, to restrict the use of hand-held transceivers in

and around the ICU, and to move the ventilators nearer to the interior walls to increase the distance from vehicle radios.

10.3.2 Interference from cellular telephones

In a 1993 incident associated with a hospital in Chicago, a portable infant ventilator shut down when a cellular telephone was being operated. In this incident, an infant on ventilator support was being transported in a car, and the infant's parent was using a cellular telephone. Testing showed that transport ventilators would shut down whenever a cellular telephone was being operated in the transceiver mode. The action taken was to restrict the use of cellular telephones during transport or near any areas of the hospital in which ventilators were in use. Further testing at the hospital revealed that other medical equipment was also affected by two-way radios, and the restrictions were expanded.

In 1994, a near-miss incident occurred at a Midwest hospital. A father asked to use his cellular telephone in a NBICU where several ventilators were in use. The Clinical Engineering Department was consulted, and permission to use the cellular telephone was refused because the Clinical Engineering Department was uncertain about possible problems. Later, when the ventilators were tested, it was found that cellular telephones would cause ventilators to shut down, with false loss-of-oxygen and loss-of-air alarms. Testing of other medical devices with both two-way radios and cellular telephones verified that additional medical equipment was sensitive to RF. As a result, two-way radios and cellular telephones were banned from the NBICU.

10.4 Infant radiant warmers

10.4.1 Interference from FM radio transmissions

In an incident reported at the 1994 AAMI Annual Meeting and subsequently published in the AAMI journal (Segal et al., 1994), it was found that an outside RF transmitter affected the temperature control circuit in infant radiant warmers. It was noted that the temperature control indicator light on some units would indicate a change whenever someone walked near a window. Testing showed that FM radio transmissions from an antenna on a nearby hill were causing interference. Some radiant warmers were found to be more sensitive than others, but the contributing circuit or construction variables could not be identified. The affected units were removed from service.

10.4.2 Interference from two-way radios and cellular telephones

In January 1995, at a hospital in the Southwest, testing was performed in an effort to duplicate the EMI effects of wireless transmitters on medical devices reported in the December 1, 1994 television program *Eye to Eye with Connie Chung.* The hospital's testing involved a similar type of infant radiant warmer and its response to an imposed electromagnetic field produced by (a) a two-way radio (hand-held transceiver) and (b) a cellular telephone. It was found that the hand-held transceiver affected the infant warmer at distances up to 10 feet, depending on the transceiver's battery charge. The cellular telephone affected the device only if it was located within 18 inches of the infant radiant warmer.

The Clinical Engineering Department wanted to determine the degree of interference: Was it isolated to the indicator module of the infant radiant warmer, or was there a relationship between the elevated temperature indicated and the actual temperature? To assess whether the heating circuit was actually engaged, the

current drain of the device was monitored. When a warmer temperature was displayed by the temperature indicator, as the hand-held transceiver or cellular telephone was transmitting, the current consumed by the device was higher, proving that the heater had been turned on.

Based on these tests and others performed on infusion pumps, PCA pumps, infant ventilators, and monitors, the Clinical Engineering Department recommended that the hospital's Safety Committee restrict the use of hand-held transceivers and cellular telephones in certain areas of the hospital. Videos were presented to the Safety Committee to provide evidence of the interactions. The Safety Committee subsequently imposed restrictions on the use of hand-held transceivers and cellular telephones in the critical care, labor and delivery, nursery, respiratory care, EEG, EMG, and cardiology areas of the hospital. (Hand-held transceivers can be used to receive in those areas, but to transmit only in unrestricted areas. Cellular telephones must be turned off.) Memos and letters were sent to physicians and to the directors of the affected departments to explain the need for the restrictions.

10.5 Mass spectrometer remote display terminal

At a hospital in the Mid-Atlantic region, a patient data logging system was installed in ORs to assist the anesthesiologists in record-keeping during cases and to improve information-gathering for later research. The system used a 486-type computer and a separate data acquisition module to run the software and acquire patient data from the monitoring equipment. To facilitate setup, an attempt was made to use the wireless network connection already being used in the building for patient information charting and retrieval. The Biomedical Engineering Department was not consulted in advance. Computer network people and physicians planned and implemented the setup, and Biomedical Engineering was called when problems occurred.

The computer, data acquisition module, computer display monitor, and isolated power supply were all mounted on an anesthesia machine. Patient monitoring equipment was also mounted on the anesthesia machine. The computer was mounted against one side of the machine and down near the floor. The data acquisition module was on a top shelf near the patient monitor. There was also a connection to a central mass spectrometer system, with a remote display terminal mounted on the anesthesia machine near the monitor.

During use, the mass spectrometer display terminal locked up completely. Operation was restored only when the computer was turned off. The interference was believed to be due to the Wireless Network Interface Card installed in the computer. It operated in the 902-928 MHz frequency band. Nominal radiated power was 1 W spread spectrum. The antenna was a 1/2-wave dipole stick attached to the rear of the computer. (It was about 5 feet from the mass spectrometer remote display.) This particular card was operating at a 911 MHz center frequency using a data transmission rate of 344 kb/sec.

The system worked satisfactorily when tested in a different OR, but the problem occurred in a lead-lined room where the system had trouble maintaining a link with the wireless network routers in the OR hallways.

The hospital abandoned the attempt to use the wireless network for this application and provided a wired connection for connecting the equipment used in the OR into the network. The manufacturer of the mass spectrometer remote display terminal now offers a software upgrade to minimize the effect of interference.

10.6 Telemetry patient monitoring systems

10.6.1 Interference from a cordless telephone

In 1994, a hospital experienced extensive EMI to a telemetry unit in the ICU. This interference was traced to a cordless telephone that was in use in the hallway.

10.6.2 Interference from a fire alarm system

In 1995, an investigation was performed to identify the cause of intermittent alarm conditions ("Cannot Analyze") in a telemetry patient monitoring system located at a nursing station. Biomedical Engineering determined that the erroneous alarms occurred only when the recently installed Simplex fire alarm system was in an alarm state. The source of interference was found to be narrow pulses corresponding to activation of the alarm audio/visual indicator. Two electrical junction boxes associated with the fire alarm system that were located in a mechanical area one floor (approximately 10 feet) below the patient monitoring system were missing cover plates, and one of the junction boxes had an approximately 18-inch loop of exposed wire. When the 18-inch loop was pushed into the junction box and the missing cover plates were replaced, the interference ceased. However, Biomedical Engineering thought that the erroneous alarm conditions could recur if a similar telemetry patient monitoring system were located closer (than 10 feet) to a component of the fire alarm system.

10.6.3 Interference from two-way radios

In September 1995, at a hospital in the Southwest, unreconciled loss of signal from the telemetry system occurred. The system had been recently installed, and various hypotheses were presented about the causes of the problem. In cooperation with the vendor, the distributed antenna system was reevaluated, with the result that five antennas were added to the design. The antenna system was tuned and balanced. When testing was performed to determine whether there was interference from either cellular telephones or two-way radios, it was discovered that a hand-held transceiver could cause gross dropout of the signal to the central monitoring station when the hand-held transceiver was transmitting on the floor above, on the floor below, or on the same floor at the far side of the building. Warning memos were distributed to all directors and head nurses, alerting them to the problem. Engineering personnel revised their procedures for responding by radio, and contractors were notified of the restriction.

Annex A

Model EMC/EMI policy and guidance for developing EMC/EMI policies

This section provides a model policy for EMC/EMI within health care facilities, as well as guidance that can be used by health care organizations in the development of EMC/EMI policies and procedures that are tailored to a specific health care facility. There is no practical way to completely eliminate EMI under all possible circumstances; however, this model policy is intended to be used to mitigate risks associated with medical device EMI that may be caused by the presence of radiated electromagnetic energy (e.g., radio) sources. Health care organizations are encouraged to freely adapt any of the text below and customize it for their particular circumstances, taking into consideration the individual facility's physical characteristics and the institution's organizational structure and resources available to devote to EMC/EMI issues. Health care organizations may also want to incorporate additional appropriate information that appears elsewhere in this TIR. The final policies and procedures that are developed for a specific institution should be well communicated and coordinated within the facility.

The model EMC/EMI policy is organized into six sections: Purpose, Applicability, Responsibilities, Abbreviations and Definitions, EMI Mitigation and EMC Management, and References. Each section includes a discussion of the intent of the section. Curly-bracketed {} text denotes further guidance or optional information, and square-bracketed [] text denotes text that should be replaced with wording appropriate for the specific institution. The Intent sections and the bracketed text may be useful in tailoring any of the model text used during development of policies and procedures for a specific health care institution. When planning and implementing its policies and procedures, the health care organization should consider availing itself of outside resources (e.g., EMC/EMI professionals).

Model policy and guidance to promote electromagnetic compatibility and mitigate medical device electromagnetic interference in health care facilities

I Purpose

***Intent**:*
It is imperative that the EMC/EMI policy clearly state its intended purpose. This should include the reasons that EMI is a concern for electronic medical devices and generally how the institution intends to promote EMC and mitigate EMI. The statement of purpose should mention that the policy will also provide guidance on the purchase, leasing, renting, and borrowing of any equipment that has the potential to be a source of EMD (e.g., wireless computer, communications, patient monitoring systems). Information contained in the policy must reflect the institution's commitment to, and approval of, administrative policies.

The purpose of this policy is to promote medical device EMC and minimize the risk of potential performance degradation of electronic medical devices resulting from EMI. It emphasizes EMC/EMI education and awareness; management of potential sources of EMD; and establishment of mechanisms for mitigation of EMI, management of facility equipment for EMC, and tracking of EMI occurrences. At the same time, it strives to achieve a balance between the need for necessary radio communications and prevention of EMI. This policy also provides guidance on the purchase, leasing, renting, and borrowing of

any equipment that has the potential to be a source of EMD (e.g., wireless computer, communications, patient monitoring systems).

{In addition to the purpose statement itself, it is usually helpful to include some background information explaining the problems that might arise from medical device EMI, and why the staff, patients, visitors, vendors and others in and around the facility need to be aware of the concerns.}

II Applicability

***Intent**:*
The intent of this section is to define the scope and responsibilities of the policy. The text should clearly define the extent of coverage by the policy (e.g., tenants and satellite activities), and any exceptions or exclusions (e.g., segments of the personnel or departments such as administration office areas). Restrictions that may be imposed on the use of RF sources will generally be applicable in designated areas directly involved in the delivery of patient care, those areas providing services that may directly impact patient care if devices in the area could be affected by EMI (e.g., clinical laboratories), and possibly places adjoining such areas (e.g., the floor above or below, or beyond a wall). Areas where there are concentrations of electrically-powered medical devices are the focus (e.g., ICU, CCU, OR, ER, neonatal units, and catheterization labs). However, unless there is a demonstrated need (e.g., located adjacent to patient care areas), these restrictions will not usually be necessary in many nonclinical areas such as administration, housekeeping, utility, and physical plant.

This policy is applicable to all elements and personnel assigned or attached to the health care facility, its tenants, and its satellite activities. [List areas of the facility to which restrictions on the use of RF sources apply and areas to which they do not apply.]

{To the extent defined in the section on EMI Mitigation and EMC Management (below), imposed restrictions are applicable to staff and employees, patients, visitors, and outside personnel (such as vendors, repair persons, and emergency personnel).}

III Responsibilities

***Intent**:*
This section sets forth the division of responsibilities within (and perhaps to some extent without) the institution to assess the EMC/EMI situation, develop plans, and implement policy. It is incumbent on the institution, through their designates, to establish the extent of the facility policies and identify those to be responsible for implementation and enforcement of EMC policies and procedures. It is suggested that an EMC/EMI Overwatch Committee be established to oversee the development of EMC/EMI policy, and report to the institution's administration. For smaller institutions, with fewer resources, an Overwatch function for EMC/EMI may be put under the authority of the Safety Committee or other standing committee.

Because of their responsibility for the safe functioning of medical devices, it is suggested that the Clinical/Biomedical Engineering Department be the focal point for the development and implementation of EMC/EMI policies. The institution should also involve facility management, information systems, materials management, risk management, and communications services

personnel, particularly those who are knowledgeable about radio transmissions and EMI mitigation.

The [name of institution] administrator has [or will] established an EMC/EMI Overwatch Committee {or designated this activity to another internal body; e.g., the Safety Committee} to address the issues of medical device EMI and EMC of electrically-powered equipment used in the facility. The Overwatch Committee has designated [name of individual or department] as the EMC Coordinator. In conjunction with the Overwatch Committee, the EMC Coordinator is responsible for developing and implementing polices and procedures to reduce the potential for patient and personnel risk resulting from medical device EMI. These responsibilities include: assessing the potential for interference with electronic medical devices under the control of [name of institution]; educating staff, patients, visitors, and other appropriate personnel; and promoting EMC of electrically-powered equipment through appropriate management and EMI mitigation. Further, the [EMC Coordinator or EMC/EMI Overwatch Committee] has the responsibility for coordinating, communicating, and monitoring the policies and procedures in a manner that enhances patient and personnel safety. These policies and procedures should be reviewed and adjusted on a periodic schedule and/or as needed.

IV Abbreviations and Definitions

Intent:
This section should define any terms used in the policies and procedures with which the staff may not be familiar, particularly EMC terminology and abbreviations.

{Refer to the abbreviations and definitions section of this TIR.}

V EMI mitigation and EMC management

Intent:
This section states the specific policies and procedures of the institution to address medical device EMC/EMI. The information in this section should be viewed as dynamic and reactive to the needs of the institution, recognizing changes in the electromagnetic environment and in device technology.

Management of potential risks of EMI to medical devices begins with an assessment of existing and potential RF sources and development of an appropriate plan to minimize these risks. Essential to minimizing EMI risk, without compromising health care and needed communications, is to identify and manage the RF sources in a way that maintains adequate separation between RF sources and electronic medical devices. Below are actions that can aid in identifying RF sources, managing these sources, and mitigating potential EMI.

With regard to ad hoc radiated RF immunity testing, each health care organization must determine its own priorities for performing any ad hoc testing. Given the competing priorities within health care organizations, it is recognized that it may not always be practical to perform this testing on a large portion of the inventory of electrically-powered medical devices. Refer to section 8.2.3 of this TIR for guidance on prioritization of devices for ad hoc testing. Health care organizations are encouraged to assess their EMI risks and develop a plan for ad hoc testing as appropriate.

Activities covered by this policy are:

A EMC/EMI education and awareness;
B Identification of RF sources;
C EMC management;
D EMI incident reporting and investigation.

The [EMC Coordinator or EMC/EMI Overwatch Committee] will report through the clinical staff to the facility administrator or board of governors.

A EMC/EMI education and awareness

Training should be conducted by experienced personnel knowledgeable about EMC/EMI issues specific to medical devices and health care facilities.

1 All employees will receive an EMC/EMI briefing within one year of the effective date of this policy and will maintain valid competency relating to EMC/EMI issues.

2 Staff, patients (including home care patients), and visitors should be educated regarding the nature of EMI and how they can recognize and help prevent it.

3 Repair personnel should be trained in proper equipment servicing to ensure that EMC integrity is maintained.

4 Vendors, emergency services, and other services who regularly enter clinical areas (e.g., law enforcement personnel) and are likely to use wireless communications equipment should be advised of the institution's policies and procedures governing the use of RF transmitters.

B Identification of RF sources

The [EMC Coordinator or EMC/EMI Overwatch Committee] assumes the responsibility for seeing that the steps listed below are carried out, and reviewed as needed, to identify potential sources of EMI.

The clinical/biomedical engineering staff should identify the RF sources most likely to influence electronic medical devices within the health care facility. If RF measurements are made, the frequency, field strength, date, time, and location should be recorded.

A list of RF sources in each of the following categories should be established and updated as new communications equipment is brought into service.

1 On-site portable and mobile RF sources (e.g., hand-held transceivers [walkie-talkies], cellular and PCS telephones, pharmaceutical robots, RF identification tags, wireless LANs, medical telemetry transmitters);

2 On-site fixed RF sources (e.g., rooftop paging transmitters, repeaters for land mobile communications, cellular and PCS base stations);

3 Outside portable and mobile RF sources likely to be in the vicinity (e.g., two-way radios in ambulances, police and fire vehicles, taxis, shuttle buses);

4 Outside fixed RF sources (e.g., pager transmitters, cellular and PCS base stations, radio and television broadcast transmitters).

C EMC management

Mitigation of medical device EMI in [name of institution] shall be achieved by management of RF sources and management of the EMC of all electrically-powered equipment used in the facility.

The EMC Coordinator, [in consultation with the EMC/EMI Overwatch Committee,] assumes the responsibility to see that the procedures listed below to manage the electromagnetic environment of the facility are accomplished.

1 In order to minimize the risk of EMI in and around areas of the facility where critical medical devices are used, including [list applicable areas, e.g., OR, ER, ICU, CCU, Neonatal unit], the following precautions should be [will be] observed: portable transmitters such as two-way radios (e.g., walkie-talkies) must be used only to receive, and cellular and PCS telephones (having an output power of 0.6 watts or more) must be switched off.

{In order to provide for communication in these areas, alternatives such as house phones and pay phones should be made available.}

2 Consideration should be given to providing pay telephones near driveways and on loading docks to allow delivery personnel to contact their dispatchers without using radio transmitters.

3 Fixed RF transmitters (e.g., roof-top transmitters) found to disrupt the performance of electronic medical devices within the facility should be removed, if possible. If it is impossible or impractical to relocate, alter, or remove those RF sources that cause medical device performance degradation, then some form of protective EMI shielding should be considered. If RF shielding is installed, RF propagation patterns are affected both inside and outside the shielded area. Unless RF-absorbing material is used, portable transmitters may need to be used with caution in or prohibited from the shielded areas. Any plans for protective EMI shielding must be cleared with the EMC Coordinator.

4 Before purchase [and/or leasing/renting], all electrically-powered equipment (e.g., medical, communications, building systems, information technology) ordered for use in the facility must be appropriately coordinated [e.g., with the EMC Coordinator] to ensure that the equipment conforms to EMC standards and is compatible with electrically-powered medical devices in the intended areas of installation or use.

a) In order to minimize the EMI risk, the EMC Coordinator should be given [has] the authority to restrict equipment purchases. Equipment purchased should conform to present EMC standards. For medical electrical equipment, IEC 60601-1-2 (1993) specifies a general immunity test level of 3 V/m. Product-specific EMC standards may contain more stringent or more lenient requirements. Because of the uncertainties involved in EMC measurements, the variation in medical devices, and allowances in IEC 60601-1-2 (1993), medical devices that meet these standards can have a higher

or lower immunity. IEC 60601-1-2 (1993) also allows wide latitude in the performance of the medical device, during the test, that can be claimed to meet the requirements of the standard. Therefore, the biomedical equipment service and repair manager/supervisor [or Clinical/Biomedical Engineering] should examine the EMC test report to determine the claimed immunity of the device, the acceptability of the pass/fail criteria used, and how the medical device performed during the test.

{The EMC Coordinator may request that the Clinical/Biomedical Engineering Department perform ad hoc RF immunity testing (per section 6 below) when there are concerns that the selected device, despite meeting present EMC standards, may fail to perform adequately in a particular environment within the institution.}

b) To reduce the risk of medical device EMI, RF transmitters purchased for use in the facility should have the lowest possible power rating that can be used to accomplish the intended purpose. For example, the facility should consider providing low-power (e.g., less than 100 mW) cellular or PCS telephones {integrated with the facility's internal telephone system} instead of hand-held transceivers (e.g., 5 W walkie-talkies) or higher-power (e.g., 600 mW or greater) cellular or PCS telephones for health care employees who need wireless communications.

5 The EMC Coordinator should be consulted prior to the installation and servicing of all electrically-powered medical and nonmedical equipment, communication systems, computers, LANs, and other intentional or unintentional sources of RF emissions that may be located near electronic medical devices.

6 On-site, ad hoc radiated RF immunity testing (performed according to the present version of ANSI C63.18) should be considered when EMI is suspected, when RF transmitters are likely to operate in proximity to critical-care medical devices, in pre-purchase evaluation of new types of RF transmitters to determine their effect on existing medical devices, in pre-purchase evaluation of new electronic medical devices, and when checking for age-related changes in medical device RF immunity. Ad hoc testing can be used to estimate the minimum distance that should be maintained between a specific RF transmitter and a specific medical device to mitigate EMI. The results of any ad hoc radiated RF immunity testing should be taken into account during revision of these policies and procedures.

7 Electronic medical devices used in intense electromagnetic environments, such as near ambulance radios or in electrosurgery, should have EMC specifications suitable for these environments.

8 EMC must be considered in the location of health care units and electrically-powered medical devices within the facility and in site selection, design, construction, and layout of new facilities.

9 All equipment users and service personnel must follow the manufacturer's recommendations, as outlined in the appropriate literature, to avoid degrading the EMC characteristics of the devices they use and maintain.

a) Equipment servicing personnel and contractors must ensure that shielding and other EMC components are not defeated, compromised, or omitted during servicing.

b) Manufacturer-specified replacement parts, cover plates, screws, and hardware must be used. Shortcuts such as leaving off cover plates, mounting screws, or shielding to allow rapid re-entry to a device's internal components should be avoided.

D EMI incident reporting and investigation

1 All suspected incidents of medical device EMI must be reported to the EMC Coordinator.

{It is recommended that the mechanism for this reporting be well disseminated to all departments and be an integral part of the education efforts.}

2 The EMC Coordinator should assure that EMI incidents are reported to the equipment manufacturer and to regulatory authorities. Refer to [health care organization's Facility Incident Reporting Policy and Procedure].

3 The EMC Coordinator should investigate incidents, make recommendations, and report findings to the EMC/EMI Overwatch Committee.

4 The EMC Coordinator should establish a methodology to track "NPF" reports by the location, date, and time of the reported malfunction, if practical, to determine whether EMI may have been involved. Equipment service personnel should report incidents of NPF to the EMC coordinator.

VI References

Intent:
The policy should reference additional sources of information. The bibliography contained in this AAMI TIR is rich with citations of such sources. However, the rapid changes in the electromagnetic environment and in device technology make it necessary to periodically update this bibliography. Clinical/biomedical and other engineering staff are encouraged to stay current by following industry journals and magazines and participating in professional and standards organizations, such as AAMI.

{Refer to annex B of this TIR.}

Annex B
(informative)

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NOTE—Various EMC products and services are listed in the *Compliance Engineering Annual Reference Guide* and the *International Journal of EMC (ITEM).*

Annex C
(informative)

Overview of surveys of electromagnetic environments associated with health care facilities

Since the early 1970s (Frank et al., 1971) there have been numerous surveys undertaken to characterize the electromagnetic field levels found within hospitals and near to the exterior of hospitals, and there has been at least one study of the electromagnetic fields that may be present inside and outside ambulances. Twelve hospital studies and one ambulance study are listed as references to this overview, and some of the results of these studies are discussed below. For the ambulance and hospital studies, the outside and inside electromagnetic environment are discussed separately, and the data from the hospital interior are subdivided to note whether the source of the electromagnetic energy was external or internal to the hospital.

The ambulance survey (Boyd et al., 1995) established that both outside and inside of the patient care compartment of a standard ambulance, the field strength can consistently exceed 3 V/m. Principally, the source of these fields was the on-board communications equipment (vehicle antenna in particular). The investigators measured field strengths up to 22 V/m inside a model of ambulance with a fiberglass roof and up to 18 V/m outside ambulances.

Of the 12 hospital studies listed below, six attempted to characterize the electromagnetic environment at one or more points outside of the hospital building (Boisvert et al., 1991; Kimmel and Gerke, 1995; Kole, 1994; Segal et al., 1994; Vlach, 1994; Vlach et al., 1995a). With only a few exceptions, the results of these studies characterized the outside of their hospitals as having low electromagnetic field strengths. To the extent that a significant electric field was encountered, the typical sources were television and FM radio broadcast transmitters located less than 1 km away. In the worst case (Vlach et al., 1995a), a line-of-sight propagation from a nearby transmission tower to the entrance of a Montreal hospital produced a measured field strength of 5.3 V/m.

At least eight hospital studies recorded the electric field inside hospitals and noted whether the source of the electromagnetic energy was external or internal to the hospital itself. The studies characterizing the fields from external sources (Boisvert et al., 1991; Foster et al., 1996; Kimmel and Gerke, 1995; Kole, 1994; Segal et al., 1994; Vlach, 1994; Vlach et al., 1995a; Vlach et al., 1995b) generally reported that external RF generators were not significant contributors to the electromagnetic ambient within the hospital unless television or FM radio broadcast transmitters or mobile radio base stations were located nearby. The Foster, Vlach, and Segal studies noted that such transmission antennas had the potential to produce “hot spots” of radio energy near hospital windows located in a direct line-of-sight. In one Philadelphia hospital (Foster et al., 1996) a maximum inside electric field of 2 V/m was recorded at a window that looked out at a paging antenna mounted on a hospital roof.

Several of the hospital surveys attempted to characterize the electromagnetic environment created by sources internal to the hospital itself. When the results of these surveys are pooled together, in-hospital sources can be subdivided into two categories: medical devices; and portable, mobile, and fixed wireless communication equipment. Of the surveys that noted specific medical devices as the sources of internal electric fields (Foster et al., 1996; Kimmel and Gerke, 1995; Kole, 1994; Miller et al., 1995; Nelson et al., 1994), the Kimmel and Gerke study appears to be the most comprehensive. This research reports that, generally, the electric fields from x-ray, laser, MRI and CT scanning equipment are very low, unless a

probe is located right next to an associated digital readout display. Also noted was that the radiated field produced by powerline disturbances was almost zero. While most medical equipment did not contribute significantly to the hospital electromagnetic environment, such cannot be said for the electrosurgical unit. For example, Kole and Nelson reported fields as high as 30 V/m and 44 V/m (respectively) within one meter of such equipment.

Most of the hospital studies concluded that wireless communication equipment generally, and 4-6 watt hand-held transceivers in particular, had the potential to dramatically increase the electric field in proximity to the transmitter. For example, in studies where 6-watt walkie-talkies were tested (Foster et al., 1996; Kimmel and Gerke, 1995; Segal et al., 1994) it was found that such a transceiver could produce an electric field of 3 V/m even at distances as large as 19 feet. Certain models of cellular telephones that were modified to maximize their RF output were found to produce electric fields of 3 V/m at a distance of 6 feet.

Generally, these surveys concluded that the greatest sources of electromagnetic energy that could disrupt the functioning of electronic medical devices are those located within the hospital itself and located within and close to ambulances. Within the hospital, portable and mobile wireless communication equipment and electrosurgical equipment pose the greatest risks. For ambulances, roof-mounted and fender-mounted antennas are the most problematic.

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