

NEWS

Environment of Care

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JOINT COMMISSION
RESOURCES

EC Revisions Approved

Annual equipment PM dropped

Patient safety clarified, preconstruction risk assessment added

At its February 8, 2001, meeting, the Joint Commission's Standards and Survey Procedures Committee approved several items that directly affect the environment of care (EC) standards. The standards address patient safety, medical equipment maintenance, and preconstruction risk assessment activities. Medical equipment maintenance revisions will go into effect July 1, 2001. Patient safety clarifications and preconstruction risk assessment requirements will go into effect January 1, 2002.

Patient safety: No new program

Revisions made to EC standards' intent statements in the *Comprehensive Accreditation Manual for Hospitals: The Official Handbook (CAMH)* clearly link those EC standards with the recently approved CAMH patient safety standards, which directly address organizationwide patient safety and medical/health care error reduction activities.

The revisions require that existing EC monitoring and response activities—activities that hospitals are currently performing—be integrated into the organization's

patient safety program. The new patient safety standards do *not* in any way call for a new, separate patient safety program.

The responsibility for directing this integration belongs to the individual assigned by the organization's leaders for directing ongoing, organization-wide collection of information about deficiencies in and opportunities for improvement in the environment of care, such as environmental risks, failures, accidents, and incidents, as per EC.4.1 in the CAMH. The patient safety and medical/health care error reduction standards are conceived as a "virtual" patient safety program that includes and integrates existing safety functions and initiatives.

At this time, the revisions to intent statements for standards EC.4.1 through EC.4.3 affect hospitals only.

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Revisions Approved

(continued from page 1)

Equipment maintenance

To provide increased flexibility to organizations regarding equipment preventive maintenance, clarifications to EC.1.6 are presented.

Specifically, EC.1.6 states that the medical equipment management plan should establish maintenance strategies for all equipment on the inventory, and it specifies that organizations may use different maintenance strategies as appropriate. For example, predictive maintenance, interval-based inspections, corrective maintenance, and metered maintenance may be effective.

Intervals for inspecting, testing, and maintaining appropriate equipment on the inventory should be based on criteria such as manufacturers' recommendations, risk levels, and current organizational experience.

"Appropriate" equipment is any equipment on the inventory that would benefit from scheduled activities to minimize the clinical and physical risks.

Annual equipment PM requirement discontinued

The intent statement for EC.2.10.3, addressing equipment maintenance, has been revised to eliminate requirements for annual (regularly scheduled) preventive maintenance (PM).

Instead, a new requirement is introduced that links maintenance requirements to strategies that are identified in the equipment management plan.

The old equipment maintenance standards had required each organization to schedule regular inspections that included testing and maintenance of medical equipment included in the organization's medical equipment

EC Standards—New and clarified language

EC safety integrated with patient safety

Revisions to Standards EC.4.1–EC.4.3 for the CAMH—Effective January 1, 2002

Standard

EC.4 The organization evaluates and improves conditions in the environment.

EC.4.1 The organization collects information about deficiencies in and opportunities for improvement in the environment.

Intent of EC.4.1

The organization's leaders assign an individual to monitor and respond to conditions in the organization's environment. The individual:

- a. addresses ongoing, organizationwide collection of information about deficiencies and opportunities for improvement in the environment of care;
- b. directs the integration of assessment of care, monitoring and response activities into the organizationwide patient safety program; (etc.)

Standard

EC.4.2 The organization analyzes identified environmental issues and develops recommendations for resolving them.

Intent of EC.4.2

Safety issues are analyzed in a timely manner.

Recommendations are developed and approved. Safety issues are communicated to the leaders of the organization, and individuals responsible for performance improvement activities, and when appropriate, relevant components of the organizationwide patient safety program. Based on the ongoing monitoring of performance in each of the seven management areas, recommendations for one or more performance improvement activities are communicated at least annually to the organization's leaders. (etc.)

Standard

EC.4.3 The organization implements recommendations to improve the environment and monitor the effectiveness of the recommendation's implementation.

Intent of EC.4.3

Appropriate staff participate in implementing recommendations and monitoring the effectiveness of the recommendations' implementation. Measurement guidelines are established by appropriate staff and results from measurement are reported through appropriate channels, including the organization's leadership and (when appropriate) relevant components of the organizationwide patient safety program. Measurement results are reported to the multidisciplinary improvement team that is responsible for resolving environment of care issues.

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inventory. However, the safety and reliability of medical equipment has improved greatly over the past decade and continues to improve as new equipment is introduced. Consequently, the need for traditional PM and scheduled safety testing for many types of contemporary medical equipment has changed. Not all medical equipment benefits equally from "interval-based" scheduled PM or inspections. (See "Data-Driven Preventive Maintenance Intervals and Beyond" on page 10.)

A number of maintenance strategies are now available that serve the objective of increasing the reliability of medical equipment. These include predictive maintenance, interval-based PM, metered PM (based on hours of run time or number of images processed), and corrective maintenance (that is, repair or replace if defective).

The revisions to EC.2.10.3 permit the same flexibility allowed by the clarified equipment management standard (standard EC.1.6, above), which allows for a variety of management strategies.

The EC.2.10.3 revision affects the standards and intent statements in the hospital, ambulatory care, long term care, and behavioral health care accreditation manuals.

Preconstruction risk assessment

Construction and renovation in occupied health care facilities can result in environmental problems, including the creation and spread of contaminants. A revision to the EC.3.2.1 intent statement now requires organizations to conduct preconstruction risk assessments.

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Revisions Approved

(continued from page 3)

The revised Joint Commission language, which is consistent with soon-to-be published Centers for Disease Control and Prevention (CDC) and American Institute of Architects (AIA) guidelines, reads as follows:

When planning demolition, construction, or renovation work, the organization conducts a proactive risk assessment utilizing risk criteria to identify hazards that could potentially compromise patient care in occupied areas of the organization's buildings. The scope and nature of the activities should determine the extent of risk assessment required. The risk criteria should address the impact demolition, renovation, or new construction activities have on air quality requirements, infection control, utility requirements, noise, vibration, and emergency procedures. As required, proper controls are selected and implemented for risk reduction and to minimize impact of these activities.

This revision affects the standards and intent statements in the hospital, ambulatory care, long term care, and behavioral health care accreditation manuals.

(continued from page 3)

Equipment maintenance—Annual PM not required

Revision to the Intent Statement of Standard EC.2.10.3 for the CAMH, CAMAC, CAMLTC, and CAMBHC—Effective July 1, 2001

Standard
EC.2.10.3 Medical equipment is maintained, tested, and inspected.

Intent of EC.2.10.3

The organization maintains documentation of

- a current, accurate, and separate inventory of all equipment in the medical equipment management program, regardless of ownership;
- performance and safety testing of all equipment in the management program prior to initial use and at least annually thereafter;
- maintenance of equipment on the inventory consistent with maintenance strategies to minimize the clinical and physical risks identified in the equipment management plan (see EC.1.6).

Documentation of maintenance and inspection of equipment includes the schedule used to correct organizational practices, risk levels, and ongoing monitoring and evaluation.

Note: An organization may determine that it is not necessary to schedule maintenance or testing of equipment on the inventory based on previous experience and safety records, or other factors. The organization may determine that it is not intended to schedule testing of technologic devices and may apply a more frequent regimen to testing and maintenance for certain maintenance and inspection activities that pose and hazards are identified in the plan.

Chemical and biological and performance testing of sterilizers.

Construction and renovation—Risk assessment

Revision to the Intent Statement of Standard EC.3.2.1 for the CAMH, CAMAC, CAMLTC, and CAMBHC—Effective January 1, 2002

Standard
EC.3.2.1 When designing the environment of care, the organization uses design criteria referenced by the health care community.

Intent of EC.3.2.1

When planning for the size, configuration, and equipping the space of renovated, altered, or new construction, the organization uses

- *Guidelines for Design and Construction of Hospitals and Health Care Facilities*, 1996 edition, published by the American Institute of Architects; or
- Applicable state rules and regulations, or similar standards or guidelines.

When the condition of existing clinical needs require a renovation, the organization determines the standards and the nature of the activities, and appropriate the need for renovation and resulting to effectively use the space and equipment provided.

When planning demolition, construction, or renovation activities, the organization conducts a proactive risk assessment using risk criteria to identify hazards that could potentially compromise patient care in occupied areas of the organization's buildings. The scope and nature of the activities should determine the extent of risk assessment. The risk criteria should address the impact demolition, renovation, or new construction activities have on air quality requirements, infection control, utility requirements, noise, vibration, and emergency procedures. As required, the organization selects and implements proper controls to reduce risk and to minimize impact of these activities.

EC.1.6, Equipment maintenance—PM flexibility enhanced

*Clarifications for the CAMH, CAMAC, CAMLTC, and CAMBHC**

Excerpt from EC.1.6

The organization plans for managing medical equipment.

Intent of EC.1.6

The organization identifies how it will establish and maintain an equipment management program to promote the safe and effective use of equipment. Equipment planning includes identifying processes for

- a. selecting and acquiring medical equipment;
- b. establishing risk criteria for identifying, evaluating, and taking inventory of equipment to be included in the management program before the equipment is used. These criteria address:
 - 1) equipment function;
 - 2) physical risks associated with use;
 - 3) equipment incident history.

3) equipment incident history

Note: All medical equipment may be included in the program rather than a limited selection based on risk criteria.

- c. monitoring and acting on equipment hazard notice recalls;
 - d. monitoring and reporting incidents in which a medical device is connected with the death, serious injury, or serious illness of any individual as required by the Safe Medical Devices Act of 1990; and
 - e. reporting and investigating equipment management problems, failures, and user errors.
- f. assessing and minimizing clinical and physical risks of equipment through inspection, testing, and maintenance.

f. maintenance strategies for all equipment on the inventory;

Note: Organization may use different maintenance strategies as appropriate (for example, predictive maintenance, interval-based inspections, corrective maintenance, metered maintenance, etc).

- g. intervals for inspecting, testing, and maintaining appropriate equipment on the inventory (ie, those pieces of equipment on the inventory benefiting from scheduled activities to minimize the clinical and physical risks) that are based on criteria such as manufacturer recommendations, risk levels, current organizational experience,...

Note—The order of the bullets differs between manuals. New language appears with underlining. Old language is struck out.

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Bureau of Medicine and Surgery Department of the Navy

GUIDANCE FOR CONTROLLING ELECTROMAGNETIC INTERFERENCE IN THE MEDICAL TREATMENT ENVIRONMENT

26 November 1999

Electromagnetic interference (EMI) can cause certain sensitive medical devices to malfunction. Although this has been an identified safety and health concern for over ten years, the frequency of incidents is anticipated to increase. The reason for this is two-fold:

- Radiofrequency emitters (such as mobile and cellular phones) coming into areas where sensitive medical devices might be located; and,
- Sensitive medical devices (pacemakers, telemetry devices and implanted pumps) moving outside the confines of hospital wards.

Just last year, there were incidents that involved digital television (TV) transmissions interfering with medical telemetry systems that use TV channels, and failure of defibrillators placed in close proximity to magnetic resonance imaging (MRI) units.

These trends are expected to continue into the next millenium. The following information is an excerpt from a Food and Drug Administration (FDA) newsletter, and provides some reasonable steps for approaching EMI in healthcare facilities:

- Ensure that medical staff is aware that EMI can cause steady, momentary or intermittent disruption in the performance of medical devices or monitoring equipment.
- Carefully check manufacturer's recommendations for proper electrical hookups for avoiding EMI effects.
- When an EMI problem is suspected, contact the manufacturer for assistance in identifying and correcting problem.
- Consider preventing known sources of EMI (cellular phones, walkie-talkies, electrical motors) from coming too close to patient monitors and other sensitive electronic medical devices. This might mean posting caution warnings in some areas.
- Report medical device problems to the FDA MedWatch reporting program (1-800-FDA-1088), including those believed to be linked to interference from a recognizable source of electromagnetic energy in the vicinity.

A reference for assisting healthcare facilities for achieving electromagnetic compatibility (EMC) and reducing risks associated with EMI is:

- Technical Information Report (TIR) 18, Guidance on Electromagnetic Compatibility of Medical Devices for Clinical/Biomedical Engineers – Part 1: Radiated Radio-Frequency Electromagnetic Energy. To order go to <http://www.aami.org>

Concerted efforts in recent years by medical equipment manufacturers, electrical and electronic engineers, the Food and Drug Administration's Center for Devices and Radiological Health, (FDA/CDRH) the Federal Communications Commission (FCC), and other organizations have contributed much to maximize EMC. For additional information refer to the FDA/CDRH webpage: <http://www.fda.gov/cdrh/emc/index.html> and the FCC webpage: <http://www.fcc.gov/oet/rfsafety> Additional information is also available at: <http://homepage.seas.upenn.edu/~kfoster/interfer.htm> (Committee on Man and Radiation (COMAR) and <http://www.fda.gov/cdrh/emc/letter.html>

Extensive electromagnetic interference problems may require testing of both medical devices and the environment. There are specialists within the Electromagnetic Environmental Effects (E³) community that can assist with surveys and testing. Bureau of Medicine and Surgery point of contact for technical information on electromagnetic bioeffects may be reached at (202) 762-3448.

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Sources of Radiofrequency Interference for Medical Devices in the Non clinical Environment

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Abstract: Radiofrequency (RF) sources in the non clinical environment can expose medical devices to field strengths that exceed several volts per meter. Electric (E) field strengths were measured at typical usage sites for home or ambulatory medical devices. Isotropic, broadband E field probes and calibrated antennas with spectrum analyzers were used. Three distinct categories of RF source/exposure situations were identified: "Distant Transmitters" includes high power radio and television broadcast transmitters. These can produce field strengths that are greater than 3 V/m at distances greater than 500 meters from the broadcast antenna. "Local Transmitters" such as 25-100 watt transceivers in emergency vehicles can produce exposure field strengths of more than 3 V/m up to 10 meters from their antenna. "User Handheld Transceivers" such as handheld cellular phones and security guard transceivers radiate 0.6 to 7 watts and produce field strengths that can exceed 3 V/m at distances of over 3 meters. These field strengths all equal the minimum 3 V/m immunity level specified in the prevailing IEC-601-1-2 international medical device electromagnetic compatibility standard.

Introduction

Many types of home-use medical devices have experienced serious failures due to radiofrequency interference (RFI) in the non clinical environment (1,2). Several types of devices with the same intended use from different manufacturers have had significant RFI problems. These devices include infant apnea monitors and electrically powered wheelchairs. Engineers from the Center for Devices and Radiological Health (CDRH) have performed extensive measurements to determine the field strengths (emissions) produced by common RF sources in non clinical environments. Measurements were performed in actual or simulated, non clinical device use environments. Field strengths were found that exceeded the 3 V/m RFI immunity level specified in the IEC 601-1-2 international medical device electromagnetic compatibility standard (3). We compiled data from publications on predicted and measured field strengths. However, these were found to be inappropriate for home-use medical device RFI situations. This is due to the small distances and complex spatial relationships between the RF emitter and the device

being exposed. We determined that measurements must be performed in-house to address our specialized needs in an adequate manner.

Methods

Field strength measurements were performed at actual and simulated non clinical sites. One study was performed in homes of apnea monitor users within several kilometers of commercial FM radio or television broadcast towers. A second study was performed at an outdoor site to measure fields produced by transceivers in fire trucks, police cars, and emergency medical vehicles (ambulance vans). An empty parking lot adjacent to our laboratory building was used to perform measurements of fields strengths emitted from police cars equipped with medium-power transceivers and external antennas. With the exception of broadcast towers, electric field strengths were measured at distances of 10 meters or less from each transmitter. Isotropic, broadband field strength probes with three orthogonal, electrically short antenna elements were used. These probes (EMCO model 7122 and Amplifier Research model FP2000) have a small RF detection unit directly below their antennas, that is an integral part of the instrument. A fiber optic cable links the RF detector to a computer data acquisition system.

Measurements of emissions at distances greater than 10 meters from the RF sources were made using an active, broadband monopole antenna with an integral ground plane (Antenna Research Model RAM220A) and a spectrum analyzer. Each orthogonal E-field component was measured at each location to obtain the total magnitude of the E-field strength. All E-field measurement systems were calibrated over their entire range by CDRH in a transverse electromagnetic (TEM) cell and other standard exposure systems. Worst-case uncertainties, including the sum of all errors in instrument calibration and usage as well as errors due to measurement techniques, were less than ± 3 dB.

Results

Analysis of the data revealed three distinct categories. These categories were defined according to the nature of the RF

source and the maximum distance from the source where 3-10 V/m existed. One category, "Distant Transmitters," includes sources that produce 3 V/m or more at distances greater than 500 meters. This type of transmitter has a relatively high transmitted power. For example, a 100 kilowatt transmitter with a non-directional antenna produces over 3V/m at 500 meters. A second category, "Local Transmitters" includes sources that produce more than 3 V/m up to ten meters from their antenna. This type of transmitter delivers over 25 watts to a non directional antenna. This category includes transmitters connected to vehicle-mounted antennas, such as those used on police cars and emergency vehicles. Here the antenna may be mounted on the roof. In this case, a nearby medical device located one meter above the ground is not in the main lobe of the radiation pattern of the antenna. This can reduce exposure levels significantly. A third category, "User Handheld Transceivers" includes sources such as handheld cellular phones and security guard transceivers. These sources are often operated in close proximity to a medical device. This type of transmitter typically delivers 0.6 to 7 watts of RF power to its antenna. Field strengths exceeding 3 V/m at distances of over 3 meters can result.

Data for each of the categories of RF sources are presented in Table 1. The distance and corresponding field strength measured are listed for each situation. All measurements were made one meter above the ground. Also included in the table is information on the estimated time duration of RF transmissions throughout the day (duty factor). A high duty

factor is typical of an RF source that is transmitting almost continuously, throughout the day. A medium duty factor is defined as a situation where the RF is transmitted by the source about 5-10% of the time. A low duty factor indicates that RF transmissions are less than a minute, several times per day.

Conclusions

We measured data under realistic, non clinical use environments. These data indicate that exposure field strengths can exceed the 3 V/m susceptibility level specified in the latest prevailing international medical device EMC standard (IEC-601-1-2) for many situations.

References

1. Silberberg J. L., "Performance Degradation of Electronic Medical Devices Due to Electromagnetic Interference," Compliance Engineering (Fall 1993) pp. 25-39.
2. Ruggera, P. and E. O'Bryan, "Studies of Apnea Monitor Radiofrequency Electromagnetic Interference", Proc. Annual International Conference, IEEE Engineering in Medicine and Biology Society, Vol. 13, No. 4, 1991, pp. 1641-1643.
3. "Medical Electrical Equipment, Part 1: General requirements for safety; Collateral Standard: Electromagnetic Compatibility," International Electrotechnical Commission, IEC 601-1-2, 1992.

Table 1. Maximum Field Strengths for Commonly Encountered RFI Sources

Source	Category	Power Watts	Frequency MHz	Field Strength V/m	Distance meters	Duty Factor
Cellular Phone	User Handheld	0.6	824-849	5.3 - 2.6	1 - 2	medium
Cellular Phone Held by Person	User Handheld	0.6	824-849	3.1	1	medium
VHF Transceiver Held by Person	User Handheld	5	154	3	2.6	low
VHF Transceiver Held by Person	User Handheld	4.3	464	3	3	low
Police Car w/Trunk-Mount Antenna ¹	Local	100	39	8	6	low
Police Car w/ Roof Antenna ¹	Local	40	490	7	6	low
Ambulance Van w/ Roof Antenna ¹	Local	100	155	9	4.5	low
Fire Truck w/ Roof Antenna ¹	Local	40	155	6	6	low
Emergency Jeep ¹	Local	40	155	4	4.5	low
Broadcast TV -VHF ²	Distant	200,000	48-223	3	1000	high
Broadcast AM ²	Distant	50,000	0.5-1.6	3	1500	high
Broadcast FM ²	Distant	100,000	88-108	3	830	high

1 - Measured one meter above ground. Distance is from nearest edge of vehicle to E-field sensor location.
 2 - Calculated value for 3 V/m based on published data and confirmed by CDRH measurements.

Medical Devices and EMI: The FDA Perspective

The key to addressing EMI in medical devices is the recognition that it involves not only the device itself but also the environment in which it is used.

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THE EMI PROBLEM

An electric powered wheelchair suddenly veers off course; an apnea monitor fails to alarm; a ventilator suddenly changes its breath rate.^{1,2,3} These are just a few examples of the problems that might occur when radiated electromagnetic (EM) energy interacts with the sensitive electronics incorporated into many medical devices. Over the years, many incidents of suspected electromagnetic interference (EMI) with medical devices have been documented.⁴ In addition, recent congressional hearings⁵ and



Figure 1. Typical Electromagnetic Environment for Medical Devices.

media attention^{6,7} have heightened concern for the safe and effective use of devices in the presence of EMI. For medical devices the environment has become crowded with potential sources of EMI (Figure 1).

Because of its concern for the public health and safety, the Center for Devices and Radiological Health (CDRH), part of the Food and Drug Administration (FDA), has been in the vanguard of examining medical device EMI and providing solutions. Extensive laboratory testing by CDRH^{8,9,10} and others^{11,12,13,14} has revealed that many devices can be susceptible to problems caused by EMI. Indeed, the CDRH has been investigating incidents of device EMI and working on solutions (e.g., the 1979 draft EMC standard for medical devices¹⁵), since the late 1960s, when there was concern for EMI with cardiac pacemakers.¹⁶

The key to addressing EMI in medical devices is the recognition that it involves not only the device itself but also the environment in which it is used, and anything that may come into that environment. More than anything else, the concern with EMI must be viewed as a systems problem requiring a systems approach. In this case the solution requires the involvement of the device industry, the EM source industry (e.g., the power and telecommunications industries), and the clinical user and patient. The public must also play a part in the overall approach to recognizing and dealing with EMI.

This article briefly outlines the concerns of the Center for Devices and Radiological Health, FDA, for EMI in all medical devices with electrical or electronic systems, and focuses on the strategy developed to minimize these problems.

THE COMPLEXITY OF DEVICE EMI

As our society seeks new technology, medical devices can usually be found in the forefront. There is an ever-increasing use of electronics and microprocessors in devices of all kinds from relatively simple devices like electrical nerve stimulators to the more recent advances in imaging such as magnetic resonance imaging (MRI). In the medical industry there is a tendency toward more automation in devices to monitor patients and help perform diagnoses. Microminiaturization has revolutionized the medical device industry; smaller devices require less power and can perform more functions.

At the same time, there is a proliferation of new communications technology, personal communications systems (PCS), cellular telephones, and wireless computer links, to name a few. With these advances are coming some unforeseen problems: the interactions between the products emitting the EM energy and sensitive medical devices. Even the devices themselves can emit EM energy which can react with other devices or products.

Electromagnetic compatibility, or EMC, is essentially the opposite of EMI. EMC means that the device is

compatible with (i.e., no interference caused by) its EM environment, and it does not emit levels of EM energy that cause EMI in other devices in the vicinity. The wide variation of medical devices and use environments makes them vulnerable to different forms of EM energy which can cause EMI: conducted, radiated, and electrostatic discharge (ESD). Further, EMI problems with medical devices can be very complex¹⁷, not only from the technical standpoint but also from the view of public health issues and solutions.

A brief overview of radio frequency interference (RFI) can help to illustrate some of the variables that make device EMI so complex and difficult to address effectively. In general, the strength of the EM field at any given distance from the source of the radiated signal (transmitter) is directly proportional to the radiated power of the transmitter and inversely proportional to the distance. The role of distance from the EM energy source is highlighted by Figure 2. The relatively low power cellular telephone

creates a 3 V/m field strength at 1 m, while a more powerful hand-held CB transceiver creates the same field strength at 5 m. Further, the high power TV transmitter creates this same field strength at a distance of 1000 m. It is easy to see then, at small distances from the radiator where EM field strength can be very high, even the best-protected devices (i.e., with a high level of immunity) may be susceptible to EMI. However, the device may be susceptible to only some of the variations (e.g., frequency or modulation) in the EM energy. This is why some devices may be affected by a nearby transmitter of a certain frequency, and other devices at the same location may not be affected. Add to RFI the other forms of EMI and it quickly becomes apparent that devices can face a fairly hostile environment which can ultimately affect the patient or device user.

FDA CONCERN WITH EMI

The consequence of EMI with medical devices may be only a transient "blip" on a monitor, or it could be as serious as preventing an alarm from sounding or causing inappropriate device movement leading to patient injury or death. With the increasing use of sensitive electronics in devices, and the proliferation of sources of EM energy, there is heightened concern about EMI in many devices. While the numbers of reports with possible links to EMI have been steady, these numbers are generally not indicative of the actual occurrence of incidents. Indeed, in investigating possible EMI-related problems it is usually the case that the EM energy which caused the event has dissipated (e.g., the EM energy source was shut off or removed from the area). Only through careful measurement and testing can the true nature of EMI susceptibility be determined. The complexity of the testing and the vast range of devices involved make it a very difficult task indeed to address EMI.

The CDRH has regulatory authority over several thousand different kinds of medical devices, with thousands of manufacturers and variations of devices. The very nature of this range of devices does not lend itself to "generic" approaches. For example, an apnea monitor is very different from a powered wheelchair, in form, function, and configuration.

The EM environment that envelops the devices can vary widely, from the rural setting to the commercial setting, to the urban setting, and of course, the hospital setting. The International Electrotechnical Commission (IEC) has classified the EM environment into eight areas and defined the typical EM environment in each area.¹⁸ Within each area there are conditions for the location and power of local EM energy sources (e.g., transmitters), which, if exceeded, would result in higher EM field strengths. Table 1 indicates the general classifications and the upper range of radiated EM field strength specified for each environment.

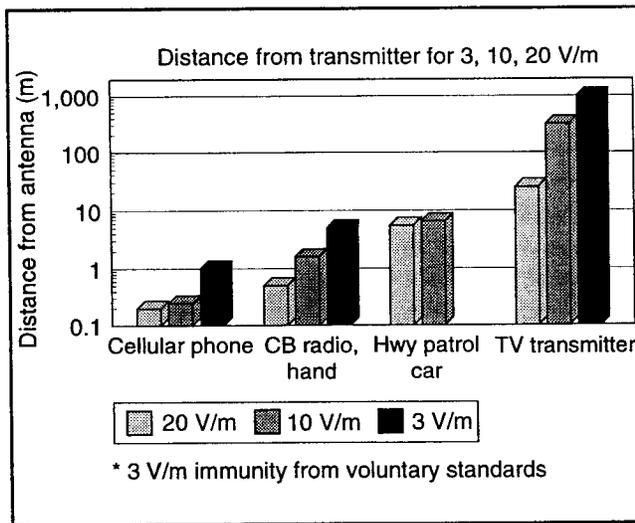


Figure 2. Radiated Field Strengths for Common Transmitters.

CLASSIFICATION	SIGNAL STRENGTH*
Residential	
Rural	up to 3 V/m
Urban	up to 10 V/m
Commercial	up to 10 V/m
Light Industrial	up to 3 V/m
Heavy Industrial	up to 30 V/m
Traffic	up to 30 V/m
Dedicated Communications Center	up to 1 V/m
Hospital	up to 3 V/m

*Frequency and source dependent, with conditions for the proximity of local radio transmitters. If transmitters exceed conditions (power, distance), then field strengths could be higher.

Table 1. IEC TC-77 Classifications of Electromagnetic Environments for Radiated Signals.

FORMATION OF THE CDRH EMC WORKING GROUP

Concern in the CDRH has led to the formation of an EMC Working Group. This group was charged by the Deputy Center Director, Dr. Elizabeth Jacobson, to:

- assess all device areas to identify EMC concerns;
- coordinate the development of a strategy to assure EMC in all appropriate devices;
- provide a focal point for actions;
- keep the Center Director and staff informed of activities involving EMI/EMC.

This initiative involves virtually all of the CDRH offices and functions. The formation and subsequent accomplishments of the group have already had an impact on the regulatory approach, research, and interactions with the device industry.¹⁹

A comprehensive plan for addressing medical device EMC needs to focus on the primary aspects of device safety and effectiveness.

The EMC Working Group has developed a draft strategy to address EMC concerns across all appropriate device areas. This involves awareness (and education), regulation, research, cooperation with other agencies and organizations, and coordination and cooperation with manufacturers and users.

PLANS FOR DEVICE EMC

A comprehensive plan for addressing medical device EMC needs to focus on the primary aspects of device safety and effectiveness. Although many manufacturers in certain device areas, such as cardiac pacemakers, have been addressing EMC for some time, discussions with users, manufacturers, and EMC test facilities personnel indicate that there still appears to be a general lack of awareness of the EMI problem. Thus, one key element in our plan includes raising this awareness and educating users, manufacturers, and regulators about EMC.

AWARENESS

The CDRH has always placed a high priority on providing information to the public. For example, when the CDRH developed information that some apnea monitors could fail to alarm due to EMI, an FDA safety alert was sent out to large numbers of clinicians and users of these devices, warning of the problem and providing tips for the safe use of the devices.²⁰ Following the extensive investigations into EMI with powered wheelchairs and motorized scooters, the FDA published an article in its Medical Bulletin, which goes to over 1 million clinicians, provid-

ing information about device EMI.²¹ In addition, a question-and-answer document was developed for the users of powered wheelchairs and motorized scooters.²²

PRE-MARKET

The pre-market approach to device regulation was charged to the former Bureau of Medical Devices by the 1976 Amendments to the Food, Drug, and Cosmetics Act. In the early 1980s, this bureau was merged with the Bureau of Radiological Health to form the Center for Devices and Radiological Health. Under the 1976 Amendments, and the more recent Safe Medical Device Act of 1990,²³ CDRH has authority to require device manufacturers to submit information about the safety and effectiveness of their devices. EMI has implications in both the safe and effective use of devices. Thus, a central part of the strategy for dealing with EMC concerns is to address these concerns in pre-market submissions.

In some device areas, notably the respiratory and anesthesia areas, concern with EMI has evolved over a period of years because of problems with such devices as the apnea monitor. Indeed, there is a draft FDA standard for apnea monitors with EMC requirements that grew out of our investigations of EMI problems. This draft standard is presently undergoing public comment.²⁴

Because of the vast range of devices, and the time and resources it takes to develop mandatory standards, a more general approach is being planned to address EMC in all appropriate device areas with respect to the pre-market concerns. This approach includes the development of priorities and guidelines for pre- and post-market and research activities.

Development of the guidelines for the regulators and manufacturers have been proposed in phases, including:

- a general guideline to address EMC across a broad range of devices which would be harmonized with prevailing national and international standards; and
- ultimately, specific guidelines tailored to concerns in each device area and developed in accordance with pre-market priorities for EMC.

POST-MARKET

For devices already in use, the post-market domain, plans are being formulated to address EMC utilizing the Good Manufacturing Practice requirements (Title 21 Code of Federal Regulations 820) and inspection guidance (FDA, CDRH Compliance Policy Guidance Manual 7382.830, 5/94). There are also plans to gather information from the manufacturers of radiation emitting products, such as electronic article surveillance systems, to examine the implications for device EMI.

In addition, the collection of incident reports, mandatory in the cases of patient death or injury,²⁵ is another major tool to assess the post-market use of devices. With the large number of devices being used today, and the

steady number of incident reports, plans are underway to better distinguish EMI incidents from other types of device incidents. The plans involve building a separate database of carefully scrutinized incident reports, which would form the foundation that would grow with later reports. A system to separate and analyze EMI reports will serve as a resource in making decisions and setting priorities.

RESEARCH AND STANDARDS

Research and work with voluntary standards organizations have been ongoing in CDRH for several years. Present investigations include examinations of reported EMI to cardiac pacemakers from digital cellular telephones, EMI to ventilator devices, and follow-up on powered wheelchair EMC. The CDRH laboratory is equipped to perform these kinds of investigations and has the experienced staff to develop test protocols. Indeed, the CDRH work with powered wheelchair EMC has contributed greatly to draft test requirements and procedures for a national (ANSI/RESNA) and an international (ISO) standard.^{25,26}

National and international standards activities play an important role in medical device EMC, which is why CDRH has promoted and supported the development of voluntary EMC product family standards for medical devices and EMC requirements for device-specific standards. In addition to ANSI/RESNA and ISO, CDRH has worked with AAMI, the ANSI-Accredited Standards Committee C63, and the International Electrotechnical Commission (IEC). In many cases, the Center's EMC laboratory findings and environmental measurements are utilized in proposals and recommendations to these voluntary standards organizations. The Center has been particularly interested and active in the development of IEC 601-1-2,²⁷ and has attempted to harmonize our recommendations with this document to the extent possible, given the FDA mandate to assure safety and effectiveness. The European equivalent of this standard will become especially important as of January 1996, when the European Community EMC Directive becomes effective.¹⁷ IEC 601-1-2 is an important step towards assuring EMC of medical devices; however, CDRH has some critical concerns about this document, and is participating in the development of the first amendment to this document.

WORK WITH OTHER AGENCIES

There are additional plans to work with other federal agencies and professional organizations to promote medical device EMC. Present activities include participation in the EMC Risk Assessment project ongoing at the Walter Reed Army Medical Center. Engineers at Walter Reed have begun an ambitious program to document the incidents of EMI in devices and to address solutions. CDRH scientists have brought laboratory data and a rich history of experience to the meetings with Walter Reed staff. In addition, CDRH is continuing its dialog with the

Federal Communications Commission (FCC) to promote medical device EMC.

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SOME ACCOMPLISHMENTS TO DATE

The CDRH EMC Working Group and others have accomplished much in a short time. Chief among the accomplishments is the formulation of strategies to address EMC in all appropriate device areas. By taking a more comprehensive approach, the CDRH has been proactive in raising awareness and concern for EMC/EMI in devices. The EMC Working Group cooperated with AAMI to present a one and one-half day forum on medical device EMC. The objective of the forum was simple: make known the concern for device EMC, and provide a forum for interaction by the users, clinicians, manufacturers, EM source industries, the public, and CDRH to address the concern.

The EMC Working Group has also been busy assessing the various device areas in the pre-market domain to help in devising priorities for guidance development and laboratory testing. In addition, the Group has provided training for the CDRH staff about EMC, developed strategies, and made recommendations for CDRH/FDA policy toward EMC. Various members of the EMC Working Group have been taking the lead in activities outside the CDRH to address EMC in medical devices.

The laboratory investigation of powered wheelchair EMI, and subsequent standards efforts, illustrates that device EMC can be achieved through cooperation among CDRH, manufacturers and users. Below is a brief overview of this work.

EXPERIENCE WITH POWERED WHEELCHAIR EMC

CDRH became aware of suspected EMI in powered wheelchairs and motorized scooters in mid-1992. By late 1993 CDRH laboratory investigations and testing had revealed serious EMI reactions by these devices over a wide range of radio frequencies (1 MHz to 1000 MHz).

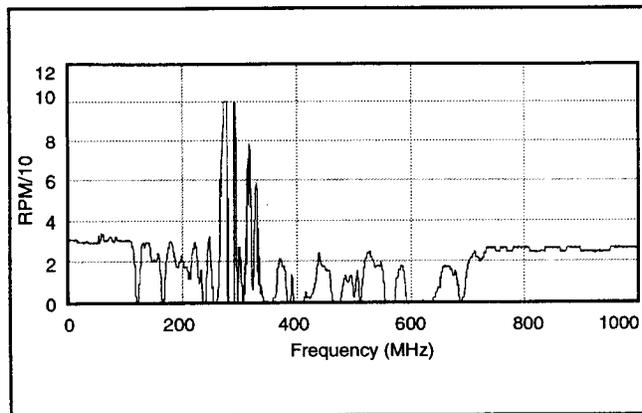


Figure 3. Test results, before EMC modifications, for sample powered wheelchair tested with the wheels in motion during exposure.

The evidence indicated that these devices could experience incidents of uncontrolled movement or electromechanical brake release in the presence of moderate radiated EM fields (as low as 3 to 10 V/m). This was sufficient to warrant notifying powered wheelchair users, through user organizations,²⁸ of the potential for EMI, and to solicit information concerning actual incidents. Further testing revealed that the EMI seemed to affect the control system of the powered wheelchairs resulting in electromechanical brake release and unintended wheel movement.

In many cases, motorized scooters utilize the same type of control systems as the powered wheelchairs. Thus, there was concern that the scooter devices could also suffer from EMI. EMC tests were performed on samples of motorized scooters. The results revealed that these devices could also exhibit EMI problems.

Experience from EMC testing of other devices led CDRH researchers to develop testing procedures which fully challenged the devices. These procedures became the basis for the 1993 CDRH proposals to the RESNA and the ISO for EMC tests and requirements in their respective standards. The proposals were made to harmonize as much as possible with the IEC 801-3 standard (recently renumbered to IEC 1000-4-3)²⁹ for radiated immunity testing. However, in the process of performing the laboratory tests, CDRH created unique procedures which take into account the relatively slow response time of powered wheelchairs. Through careful scrutiny of submissions of EMC test data by the device manufacturers, and verification testing by CDRH, it became clear that the procedures devised by CDRH were more accurate in determining EMI problems than the existing standard procedures.

Additional testing procedures were developed to examine the device response as the wheels were kept at a constant speed to simulate normal movement of the wheelchair. Figure 3 represents the results of testing on one device (before modifications were made by the manufacturer). In this case, the wheels were fixed at a constant speed of 30 RPM during the exposure of the device. Note that there are several places where the

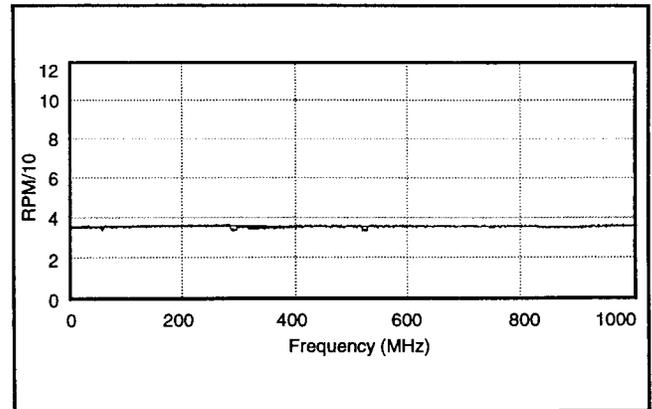


Figure 4. Test results, after modifications, for the same sample device (from Figure 3) tested with the wheels in motion during exposure.

motion of the wheels deviated from the 30 RPM baseline, indicating EMI to the wheelchair. These tests were performed at the EM field strength of 20 V/m. This level was chosen because the device manufacturers had stated they could build devices immune to this level, which is approximately the field strength from a hand-held transmitter at 0.6 m (2 ft). Many powered wheelchair users utilize radio transceivers and cellular telephones for communications, any of which could be placed within this distance of the device's control system.

Following careful EMC modifications to the powered wheelchair by the manufacturer, with the appropriate shielding and circuit modifications, the same powered wheelchair was retested and found to be immune (no EMI reactions) across the entire frequency range (Figure 4). This demonstrated that these devices could indeed be made immune to 20 V/m. With such findings in hand, CDRH notified powered wheelchair and scooter manufacturers in May 1994³⁰ that future submissions for these type devices should address EMC in labeling and testing. Additional work with the RESNA subcommittee for EMC refined the original CDRH EMC test proposal and reduced the number of test points, to make the procedure more affordable to perform, without compromising the test reliability.

The experience with powered wheelchair EMI demonstrates the ability of CDRH to work with the device manufacturers to recognize and address an EMI problem. Many of these device manufacturers were helpful in sharing information, providing samples, bringing together interested parties, and working towards a solution of the problem. CDRH was able to develop a new and more accurate test procedure in a relatively short time frame, building upon its years of experience in the laboratory and in EMC testing of devices.

SUMMARY

There is still much work to be done to reach the goal of assuring device EMC across the broad range of devices. The CDRH EMC Working Group has been charged by

the Deputy Center Director to continue this effort, which will likely last some time into the future and impact all electrical and electronic medical devices. Given the nature of the EMI problem, and the quick pace of technology, plans for this program must be dynamic and flexible. The very nature of EMI is complex, with large uncertainties in nearly every aspect. The CDRH approach will reflect these constraints and rely in large measure on the cooperation of all parties.

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COMAR Technical Information Statement

RADIOFREQUENCY INTERFERENCE WITH MEDICAL DEVICES

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ABSTRACT

The past few years have seen increased reports that medical devices, such as pacemakers, apnea monitors, electrically powered wheelchairs, etc., have failed to operate correctly because of interference from various emitters of radiofrequency energy. This condition is called radiofrequency interference (RFI). The consequences of these failures range from inconvenience to serious injuries and death. Reasons for this problem are twofold: 1) increasing numbers of electronically controlled medical devices with inadequate electronic protection against RFI, and 2) a significant increase in the number of RF sources in the environment. Medical devices are widely used outside the hospital and may be attached to, or implanted in, patients. Portable wireless communications equipment, including cellular phones, handheld transceivers, and vehicle mounted transceivers, comprise one of the largest sources of RFI. Some medical devices are especially sensitive to the type of digital modulation that some of the wireless communications devices utilize.

The prevailing international standard for the RF immunity of medical devices is the 1993 revision of the International Electrotechnical Commission (IEC) Standard IEC 601-1-2. This standard sets a minimum immunity level of 3 volts per meter (V/m) in the 26-1000 MHz frequency range. For non-life supporting devices, testing is required only at the specific frequencies of 27.12, 40.68, and 915 MHz. Technology exists to protect, or "harden," most medical devices from RF fields that are much more intense than the 3

V/m level specified in present RFI standards. Most of these techniques, including shielding, grounding and filtering, are not costly if they are incorporated into the initial design of the electronics system.

COMAR recommends that the various parties involved in the manufacture and use of RFI prone medical devices take steps to avoid serious RFI problems that may lead to safety hazards. Medical device manufacturers should design and test their products to ensure conformance with current RFI standards and educate the users of their devices about the possible symptoms of potential RFI. If there exists the possibility of RFI problems to medical devices, steps should be taken to ensure that all sources of RF energy be kept at a sufficient distance.

INTRODUCTION

Since the early 1990s, reports of medical device failure from electromagnetic interference have increased [1-4]. This is due to several factors. The number of electronically controlled medical devices has burgeoned in hospitals and other medical facilities. Newer instruments are often more sensitive to radiofrequency interference (RFI) because they incorporate low power integrated electronic circuitry that can be much more sensitive to electromagnetic fields than their electrical and electromechanical predecessors. In this document, RFI refers to radiated interference from electromagnetic fields that are coupled from a source to a medical device through the air (i.e. without connections via conductors such as wires or cables).

There has also been a significant rise in the use of electronically controlled medical devices outside the clinical environment. These devices are often used in homes, attached to patients, or implanted in their bodies. In addition, portable wireless communications equipment, such as cellular phones, handheld transceivers, and vehicle mounted transceivers, is a major source of RFI. The number of land mobile transmitters in the US alone currently exceeds 10 million and personal communications systems are burgeoning throughout the world. To an ever increasing extent, wireless communications equipment (e.g., cellular phones) is likely to be used in close proximity to medical devices without the knowledge of the patient or attending medical personnel.

Digital mobile communications systems often utilize pulsed amplitude modulation, a type of modulation, that can enhance the potential for RFI. For example, cellular telephones based on some digital technologies generate peak powers of up to 8 watts and are modulated at 2 to 217 pulses per second. This range spans the physiological frequencies of the human body, from about 0.5 Hz to several hundred Hz, that are monitored by many medical devices. This is often termed the "physiological passband." While modulation at very low frequencies is critical, this document does not address RFI from sources with very low carrier frequencies. Thus, AC power line fields (50-60 Hz) are excluded from discussion. Also excluded are transient fields, such as pulsed gradient fields from magnetic resonance imaging (MRI) systems, where most of the frequency content is below a few MHz. The frequencies discussed in this statement are in the range of 30 to 3,000 MHz.

REPORTS OF PROBLEMS ENCOUNTERED

Hundreds of incidents of RFI induced medical device failure have been reported, studied, and summarized [1,5]. The most likely source of those failures has been RFI from mobile radio transmitters. The consequences have ranged from inconvenience to serious injuries and death. However, many more

incidents may occur that are not reported because most users of medical devices are unaware that RF fields are present when problems are recognized and because of the intermittent nature of the failures that could cause them to be unobserved.

In the mid-1980s, the US Food and Drug Administration (FDA) had become aware that approximately 60 infants died in the United States while being monitored for breathing cessation by one model of apnea monitor. Subsequent tests have shown that this particular monitor is extremely susceptible to low level RF fields [6], including those from mobile communication base stations several hundred meters away and FM radio broadcast stations more than one kilometer away. Other apnea monitors have been shown to be similarly susceptible to malfunction. This has resulted in voluntary recall of more than 16,000 apnea monitors.

Another device that has demonstrated RFI susceptibility is the electrically powered wheelchair. Unintended motion has been initiated by RFI from transceivers in nearby emergency vehicles [7], causing persons to be ejected from their wheelchairs or propelled into traffic. New draft performance standards for wheelchairs are being developed by the Rehabilitation and Assistive Technology Society of North America (RESNA) to address these problems; many manufacturers are developing products that conform to these standards.

An additional problem area involves implanted cardiac pacemakers and defibrillators. Teams of engineers and cardiologists in several countries have independently studied these devices, either in patients or tissue simulating models, demonstrating that nearby digital cellular phones sometimes induce undesirable effects [8-11]. The dominant effect observed has been loss of pacemaker adaptive control, causing the device to deliver stimuli either irregularly or at a preprogrammed fixed rate. This is not usually detected by the patient and, when the cellular phones are moved away, the pacemaker resumes its normal operation. Interference with pacemakers has not been observed when the phones are held at the ear. A panel of researchers has concluded that phone/pacemaker interference should not be considered a major public health concern and has offered specific recommendations for pacemaker wearers [12-13]. Cellular phones have also been shown to cause unintended firings of implantable cardiac defibrillators [14].

Recently, handheld digital cellular telephones, that use pulse modulated time division multiple access (TDMA), have been found to disrupt the proper operation of in-the-ear hearing aids. TDMA phones include international Global System for Mobile (GSM) communications and North American Digital Cellular (NADC) pulse modulation formats, which utilize schemes that produce 100% amplitude modulated pulses of the RF carrier at frequencies within the audible hearing range. Subjective perception of interference varies from barely perceptible to annoying and loud, starting when the phones are within one meter of the hearing aids and becoming louder when the phones are several centimeters away [15]. This type of interference also occurs in behind-the-ear hearing aids, making it impossible for wearers of this device to be able to use this type of phone.

Recently, warnings have been published concerning the use of wireless communications equipment in the clinical environment. Hospitals worldwide have recommended that cellular phones and two way radios not be used in intensive care units, operating theaters, and patient rooms, where critical care medical equipment is in use [16-17]. Measurements that have been made inside an ambulance, where electronic patient monitoring equipment is used, have yielded field strengths of up to 22 V/m in the region of 800 MHz [18]. Recommendations have also been made that patients using medical equipment at home be educated about possible hazards from the simultaneous use of portable telecommunication devices. Extensive measurements have been made to determine the field strengths produced by common RF sources in actual or simulated non-clinical environments, many that are greater than 3 V/m. [19].

FACTORS THAT AFFECT THE OCCURRENCE OF RFI

Many factors affect the severity of RFI in medical devices, including 1) the coupling between a source of interference and the medical device, 2) the frequency of the RF carrier, 3) the modulation imposed on the fields from each source, and 4) the distance between the RF source and the susceptible medical device. Effects of coupling occur primarily when the susceptible device is in the near field of the source. Capacitive coupling occurs in a region near the source where the electric field is dominant (e.g. the tip of a dipole antenna). In contrast, inductive (magnetic) coupling between the base of the cellular phone antenna and implanted cardiac pacemakers has been demonstrated by Carillo et al. [11] to prevail over capacitive coupling for this situation. While coupling is a critical factor for RFI under near field conditions, in the far field it is the carrier frequency that is crucial to the introduction of RF into a device. Generally, the frequencies with the greatest ability to induce RFI are those whose wavelengths are comparable to the maximum dimension of a medical device's physical housing, or to the length of the external cables and leads connected to the patient.

Modulation also affects the degree of interference for a given set of exposure conditions; amplitude modulation (including pulsed RF) is usually the most significant for RFI. The amplitude modulated RF carrier can be detected at the semiconductor junctions in the device; significant interference occurs if the modulating frequencies are within the physiological passband of the device.

STANDARDS FOR RF IMMUNITY OF MEDICAL DEVICES

The predominant international standard for the RF immunity of medical devices is the IEC Standard 601-1-2; the 1993 revision of this standard requires a minimum immunity level of 3 V/m in the 26-1000 MHz frequency range [20]. For devices that are not life supporting, testing for compliance is required only at the specific frequencies of 27.12, 40.68, and 915 MHz. Sinusoidal amplitude modulation of 80% of the carrier is required. The modulating frequency should represent the most significant interference source to the specific device under test, or in lieu of that, 1 kHz. Susceptibility to lower frequencies should be evaluated using standardized test methods.

Test methods for radiated RFI are specified in IEC standard 1000-4-3 [21]. The primary test method involves the use of a semi-anechoic chamber and a biconical, log periodic, or other linearly polarized transmitting antenna. Exposure of the device under test must be performed in a "uniform area" of field strength that measures 1.5 x 1.5 meters, is at least 0.8 meters above the floor, is at least one meter from the exposure antenna, and is at least 0.8 meters away from any RF reflecting objects. The front surface of the device under test and all wires and cables must be placed in the uniform area. To calibrate the field strengths in this area, measurements must be

made at 16 evenly spaced points (including the four corners of the plane) with the device under test absent. The uniformity of the field must be within 6 dB for 12 of the 16 points. Wires should be arranged to be consistent with the manufacturer's recommendations. The first meter of each signal carrying cable and power cable must be extended in the planar area. The next two meters of the cable must be arranged in a non-inductive bundle. Exposures with four orientations of the device under test must be performed for both a horizontal and vertical polarization of the electric field. At least one exposure should be performed with the leads and cables aligned with the electric field vector.

Other device specific RFI standards are being, or have been, developed, including standards that address hearing aid interference from cellular phones [22] and powered wheelchair RF immunity (RESNA).

FAILURE PREVENTION AND RFI AVOIDANCE

For many years, military, aircraft, and automotive electronics systems have been required to meet strict RFI requirements for immunity to up to 200 V/m because these systems could encounter such levels during normal operations. The technology has already been developed to "harden" most medical devices against fields that are much more intense than the 3 V/m level specified in present RFI standards for medical devices. Most hardening techniques are not costly if they are incorporated into the initial design of the electronics system. Standard RF immunization techniques include the use of shielding, grounding, and filtering. Shielding includes enclosing the device in metal boxes or in plastic boxes coated with metallic paint. Use of RF shielded cables is standard practice in commercial audio and video devices. Grounding of electronics circuitry and cable shields is an inexpensive but necessary step toward ensuring RFI immunity. RF filtering of signal carrying conductors, especially in sensitive patient monitoring equipment, should be performed carefully. The potential for the success of these techniques has been demonstrated in implanted cardiac pacemakers, which commonly achieve immunity of up to 200 V/m even though these devices monitor weak electrophysiological voltages.

The use of capacitive "feed through" RF filters preceding the input circuitry of an implanted medical device is straightforward [23-24]. However, patient connected medical devices, which are powered by 60 Hz AC, must accommodate the safety requirements for electrical leakage currents as well as RFI immunity requirements. Therefore, patient connection leads on devices that obtain power from AC lines must utilize special techniques to simultaneously meet both types of safety requirements. Techniques for isolating patients, which incorporate optical or transformer coupling, may be required. In addition, designers can add interference recognition and fail-safe circuitry to their medical devices [25]. For example, many cardiac pacemakers are protected from erratic operation by being programmed to revert to a fixed rate when RFI is detected.

Mobile RF and wireless communications systems can be optimized for compatibility with medical electronics. The modulation frequencies of RF transmitters should be outside the physiological passband of most or all medical devices. Digital modulation schemes that use TDMA, and the associated amplitude modulation pulses, should be carefully designed to avoid RFI. Frequency modulation, or non-pulsed, spread spectrum modulation techniques (such as certain forms of code division multiple access, or CDMA) can be used.

Managers of facilities where sensitive medical devices are used should control RFI by careful planning and system design. For example, the radiated power of many modern handheld and portable cellular phones is under the control of the base station. When close to a base station, handheld and portable phones may operate at power levels far lower than the maximum power of 600 mW (for handheld phones) or 3000 mW (for portable bag phones). Thus, when a base station is located near a health care facility or when low power base stations (microcells) are used within the facility, cellular phones will normally operate at low power. However, the base station itself must be properly sited to avoid causing RFI. If deemed necessary, RF sources can be restricted from the more sensitive areas of a hospital, such as intensive care units.

Administrators of healthcare facilities can impose restrictions on the use of mobile RF transceivers. The concept of a specific "minimum separation distance" for each type of mobile transceiver has recently

been proposed [2,4]. For example, handheld cellular phones that radiate 600 mW would have to be kept at least one meter from a medical device that is immune to 3 V/m. A 5 watt handheld transceiver would have to be kept 2.6 meters from the same device. In practice, an additional safety factor should be required to account for enhancement of signals by field reflections.

To address RFI problems with implanted cardiac pacemakers, certain control techniques can be implemented. Even though pacemakers have been designed to be immune to very intense electric fields (200 V/m), some may still malfunction when certain cellular phones are placed within a few centimeters of the pulse generator. Therefore, government agencies have issued recommendations to health care providers and patients with pacemakers [26]. Cellular telephone manufacturers and pacemaker manufacturers have independently developed similar recommendations that indicate how to minimize the occurrence of RFI in patients with implanted cardiac pacemakers when they use cellular phones. Users should avoid placing cellular phones directly over pacemakers (such as in the breast pocket) when the phone is turned on. Also, the cellular phone should be used with the right ear if the pacemaker is implanted in the left side of the chest

RECOMMENDATIONS

COMAR recommends that manufacturers and users of both medical devices and radiofrequency transmitters work together to ensure that medical devices can operate in a safe and effective manner while in the presence of RF fields.

Medical device manufacturers should design and test their products to ensure conformance with current RFI standards so that their devices are not excessively sensitive to RFI. This will require that the products be shielded in electrically conductive, or conductor coated, enclosures that incorporate feed through filters and other techniques to increase electromagnetic compatibility. Even when medical devices conform to existing standards, manufacturers should warn both medical professionals and patients of situations where RFI failure may occur. The warning should include information that describes how to recognize the symptoms of RFI, how to deal with RFI problems, and how to report incidents.

Dialogues between manufacturers of RF emitters and manufacturers of medical devices, conducted through national and international manufacturers' organizations and standards setting committees, are encouraged to maximize timely exchange of information about new product designs and release dates. Such organizations in the United States include the Cellular Telephone Industry Association (CTIA), the Association for the Advancement of Medical Instrumentation (AAMI) and the Health Industry Manufacturer's Association (HIMA).

Continuing vigilance by both manufacturers and users of medical devices is essential to ensure RFI immunity. If a manufacturer modifies the design or physical housing, RFI immunity can change drastically. Also, during repair, the RFI immunity of a device may be altered significantly by inadvertent modifications, such as failure to replace shielding gaskets. As a general rule, users of medical devices should keep RF emitters as far away from medical devices as is practical.

A standardized RFI test method has been developed to enable engineers in clinical environments to estimate the susceptibility of medical devices to specific radio frequency transmitters in a setting comparable to that of actual use [27]. This method should be used to identify potentially problematic situations in hospitals where transmitters are repeatedly used in close proximity to critical medical

devices.

All incidents of suspected interference, especially those involving injury, should be reported in detail to the appropriate person, facility, or agency so that the manufacturer may be informed about the problem in a timely fashion. In the United States, the FDA maintains a Medical Device Reporting System [28] and other services for this purpose. All concerned parties should participate in the development or revision of performance standards that address medical device RFI. If specific concerns arise, they should be submitted, in writing, to the appropriate Standard Development Committee.

CONCLUSIONS

Today, many medical devices that are tested for susceptibility to RFI cannot meet the 3 V/m minimum immunity requirements of the current IEC Standard 601-1-2. Handheld cellular telephones produce field strengths greater than 3 V/m at distances of up to 1 meter, while higher power transceivers produce 3 V/m fields at distances of up to 2.6 meters. This situation may be responsible for serious failures of life sustaining medical devices. It is imperative that immunity to RFI be designed into new medical devices. Because mobile transceivers can generate field strengths of hundreds of volts per meter at close range, fail-safe mechanisms should be designed into medical devices that cannot be made immune to such high RF field strengths.

The field strength to which a medical device may be exposed depends on many conditions that are beyond the control of the designer or manufacturer. Therefore, administrative controls should be implemented that include education of the user, both in the clinic and at home. The possibility of incomplete RF compatibility between RF transceivers and medical devices must be recognized and dealt with. In health care facilities, mobile transceivers should be restricted to distances that have been determined to be safe, especially in areas where critical devices are operated. By developing both short and long term solutions like those suggested above, electromagnetic compatibility between mobile RF sources and medical devices can be maximized.

This statement was prepared by H.I. Bassen with significant contributions by E.R. Adair, Q. Balzano, G.J. Beers, C.K. Chou, L.N. Heynick, B.J. Klauenberg, and G.D. Lapin. It has been reviewed by members of COMAR, all of whom have expertise in the general area of the interactions of electromagnetic fields with humans. This final report was approved by vote of the full COMAR membership and by the EMB Society's Executive Committee which sponsors COMAR as a Technical Committee.

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What is radiofrequency energy (RF)?

Radiofrequency (RF) energy is another name for radio waves. It is one form of electromagnetic energy that makes up the electromagnetic spectrum. Some of the other forms of energy in the electromagnetic

spectrum are gamma rays, x-rays and light. Electromagnetic energy (or electromagnetic radiation) consists of waves of electric and magnetic energy moving together (radiating) through space. The area where these waves are found is called an electromagnetic field.

Radio waves are created due to the movement of electrical charges in antennas. As they are created, these waves radiate away from the antenna. All electromagnetic waves travel at the speed of light. The major differences between the different types of waves are the distances covered by one cycle of the wave and the number of waves that pass a certain point during a set time period. The wavelength is the distance covered by one cycle of a wave. The frequency is the number of waves passing a given point in one second. For any electromagnetic wave, the wavelength multiplied by the frequency equals the speed of light. The frequency of an RF signal is usually expressed in units called hertz (Hz). One Hz equals one wave per second. One kilohertz (kHz) equals one thousand waves per second, one megahertz (MHz) equals one million waves per second, and one gigahertz (GHz) equals one billion waves per second.

RF energy includes waves with frequencies ranging from about 3000 waves per second (3 kHz) to 300 billion waves per second (300 GHz). Microwaves are a subset of radio waves that have frequencies ranging from around 300 million waves per second (300 MHz) to three billion waves per second (3 GHz).

How is radiofrequency energy used?

Probably the most important use of RF energy is for telecommunications. Radio and TV broadcasting, wireless phones, pagers, cordless phones, police and fire department radios, point-to-point links and satellite communications all rely on RF energy.

Other uses of RF energy include microwave ovens, radar, industrial heaters and sealers, and medical treatments. RF energy, especially at microwave frequencies, can heat water. Since most food has a high water content, microwaves can cook food quickly. Radar relies on RF energy to track cars and airplanes as well as for military applications. Industrial heaters and sealers use RF energy to mold plastic materials, glue wood products, seal leather items such as shoes and pocketbooks, and process food. Medical uses of RF energy include pacemaker monitoring and programming.

How is radiofrequency radiation measured?

RF waves and RF fields have both electrical and magnetic components. It is often convenient to express the strength of the RF field in terms of each component. For example, the unit "volts per meter" (V/m) is used to measure the electric field strength, and the unit "amperes per meter" (A/m) is used to express the magnetic field strength. Another common way to characterize an RF field is by means of the power density. Power density is defined as power per unit area. For example, power density can be expressed in terms of milliwatts (one thousandth of a watt) per square centimeter (mW/cm² or microwatts (one millionth of a watt) per square centimeter (μ W/cm²).

The quantity used to measure how much RF energy is actually absorbed by the body is called the Specific Absorption Rate or SAR. The SAR is a measure of the rate of absorption of RF energy. It is usually expressed in units of watts per kilogram (W/kg) or milliwatts per gram (mW/g).

What biological effects can be caused by RF energy?

The biological effects of radiofrequency energy should not be confused with the effects from other types of electromagnetic energy.

Very high levels of electromagnetic energy, such as is found in X-rays and gamma rays can ionize biological tissues. Ionization is a process where electrons are stripped away from their normal locations in atoms and molecules. It can permanently damage biological tissues including DNA, the genetic material. Ionization only occurs with very high levels of electromagnetic energy such as X-rays and gamma rays. Often the term radiation is used when discussing ionizing radiation (such as that associated with nuclear power plants).

The energy levels associated with radiofrequency energy, including both radio waves and microwaves, are not great enough to cause the ionization of atoms and molecules. Therefore, RF energy is a type of non-ionizing radiation. Other types of non-ionizing radiation include visible light, infrared radiation (heat) and other forms of electromagnetic radiation with relatively low frequencies.

Large amounts of RF energy can heat tissue. This can damage tissues and increase body temperatures. Two areas of the body, the eyes and the testes, are particularly vulnerable to RF heating because there is relatively little blood flow in them to carry away excess heat.

The amount of RF radiation routinely encountered by the general public is too low to produce heating or increased body temperature. Still, some people have questions about the possible health effects of low levels of RF energy. It is generally agreed that further research is needed to determine what effects actually occur and whether they are dangerous to people. In the meantime, standards-setting organizations and government agencies are continuing to monitor the latest scientific findings to determine whether changes in safety limits are needed to protect human health.

FDA, EPA and other US government agencies responsible for public health and safety have worked together and in connection with WHO to monitor developments and identify research needs related to RF biological effects.

What levels of RF energy are considered safe?

Various organizations and countries have developed standards for exposure to radiofrequency energy. These standards recommend safe levels of exposure for both the general public and for workers. In the United States, the FCC has used safety guidelines for RF environmental exposure since 1985.

The FCC guidelines for human exposure to RF electromagnetic fields are derived from the recommendations of two expert organizations, the National Council on Radiation Protection and Measurements (NCRP) and the Institute of Electrical and Electronics Engineers (IEEE). In both cases, the recommendations were developed by scientific and engineering experts drawn from industry, government, and academia after extensive reviews of the scientific literature related to the biological effects of RF energy.

Many countries in Europe and elsewhere use exposure guidelines developed by the International Commission on Non-Ionizing Radiation Protection (ICNIRP). The ICNIRP safety limits are generally similar to those of the NCRP and IEEE, with a few exceptions. For example, ICNIRP recommends different exposure levels in the lower and upper frequency ranges and for localized exposure from certain products such as hand-held wireless telephones. Currently, the World Health Organization is working to provide a framework for international harmonization of RF safety standards.

The NCRP, IEEE, and ICNIRP all have identified a whole-body Specific Absorption Rate (SAR) value of 4 watts per kilogram (4 W/kg) as a threshold level of exposure at which harmful biological effects may occur. Exposure guidelines in terms of field strength, power density and localized SAR were then

derived from this threshold value. In addition, the NCRP, IEEE, and ICNIRP guidelines vary depending on the frequency of the RF exposure. This is due to the finding that whole-body human absorption of RF energy varies with the frequency of the RF signal. The most restrictive limits on whole-body exposure are in the frequency range of 30-300 MHz where the human body absorbs RF energy most efficiently. For products that only expose part of the body, such as wireless phones, exposure limits in terms of SAR only are specified.

The exposure limits used by the FCC are expressed in terms of SAR, electric and magnetic field strength, and power density for transmitters operating at frequencies from 300 kHz to 100 GHz. The specific values can be found in two FCC bulletins, OET Bulletins 56 and 65:

<http://www.fcc.gov/oet/info/documents/bulletins/#56>;

<http://www.fcc.gov/oet/info/documents/bulletins/#65>

Why has the FCC adopted guidelines for RF exposure?

The FCC authorizes and licenses products, transmitters, and facilities that generate RF and microwave radiation. It has jurisdiction over all transmitting services in the U.S. except those specifically operated by the Federal Government. While the FCC does not have the expertise to determine radiation exposure guidelines on its own, it does have the expertise and authority to recognize and adopt technically sound standards promulgated by other expert agencies and organizations, and has done so. (Our joint efforts with the FDA in developing this website is illustrative of the kind of inter-agency efforts and consultation we engage in regarding this health and safety issue.)

Under the National Environmental Policy Act of 1969 (NEPA), the FCC has certain responsibilities to consider whether its actions will significantly affect the quality of the human environment. Therefore, FCC approval and licensing of transmitters and facilities must be evaluated for significant impact on the environment. Human exposure to RF radiation emitted by FCC-regulated transmitters is one of several factors that must be considered in such environmental evaluations. In 1996, the FCC revised its guidelines for RF exposure as a result of a multi-year proceeding and as required by the Telecommunications Act of 1996.

Radio and television broadcast stations, satellite-earth stations, experimental radio stations and certain wireless communication facilities are required to undergo routine evaluation for RF compliance when they submit an application to the FCC for construction or modification of a transmitting facility or renewal of a license. Failure to comply with the FCC's RF exposure guidelines could lead to the preparation of a formal Environmental Assessment, possible Environmental Impact Statement and eventual rejection of an application. Technical guidelines for evaluating compliance with the FCC RF safety requirements can be found in the FCC's OET Bulletin 65.

<http://www.fcc.gov/oet/info/documents/bulletins/#65>

Low-powered, intermittent, or inaccessible RF transmitters and facilities are normally excluded from the requirement for routine evaluation for RF exposure. These exclusions are based on standard calculations and measurement data indicating that a transmitting station or equipment operating under the conditions prescribed is unlikely to cause exposures in excess of the guidelines under normal conditions of use. Such exclusions are not exclusions from compliance, but, rather, exclusions from routine evaluation. The FCC's policies on RF exposure and categorical exclusion can be found in Section 1.1307(b) of the FCC's Rules and Regulations [(47 CFR 1.1307(b))].

How can I obtain the Specific Absorption Rate (SAR) value for my wireless phone?

The FCC requires that wireless phones sold in the United States demonstrate compliance with human exposure limits adopted by the FCC in 1996. The relative amount of RF energy absorbed in the head of a wireless telephone-user is given by the Specific Absorption Rate (SAR), as explained above. The FCC requires wireless phones to comply with a safety limit of 1.6 watts per kilogram (1.6 W/kg) in terms of SAR.

Information on SAR for a specific phone model can be obtained for many recently manufactured phones using the FCC identification (ID) number for that model. The FCC ID number is usually printed somewhere on the case of the phone. Sometimes it may be necessary to remove the battery pack to find the number. Once you have the ID number, go to the following Web address: www.fcc.gov/oet/fccid. On this page, you will see instructions for entering the FCC ID number. Type the FCC ID number exactly as requested (the Grantee Code is the first three characters, the Equipment Product Code is the rest of the FCC ID number). Then click on "Start Search." The "Grant of Equipment Authorization" for your telephone should appear. Read through the grant for the section on "SAR Compliance," "Certification of Compliance with FCC Rules for RF Exposure" or similar language. This section should contain the value(s) for typical or maximum SAR for your phone.

Phones and other products authorized since June 2, 2000, should have the maximum SAR levels noted directly on the "Grant of Equipment Authorization." For phones and products authorized between about mid-1998 and June 2000, detailed information on SAR levels is typically found in the exhibits associated with the grant. Once a grant is accessed, the exhibits can be viewed by clicking on "View Exhibit." Grants authorized prior to 1998 are not part of the electronic database but, rather, have been documented in the form of paper records.

The FCC database does not list phones by model number. However, consumers may find SAR information from other sources as well. Some wireless phone manufacturers make SAR information available on their own Web sites. In addition, some non-government Web sites provide SARs for specific models of wireless phones. However, the FCC has not reviewed these sites and makes no guarantees of their accuracy. Finally, phones certified by the Cellular Telecommunications and Internet Association (CTIA) are required to provide SAR information to consumers in the instructional materials that come with the phones.

Do hands-free kits for wireless phones reduce risks from exposure to RF emissions?

Since there are no known risks from exposure to RF emissions from wireless phones, there is no reason to believe that hands-free kits reduce risks. Hands-free kits can be used with wireless phones for convenience and comfort. These systems reduce the absorption of RF energy in the head because the phone, which is the source of the RF emissions, will not be placed against the head. On the other hand, the phone is mounted against the waist or other part of the body during use, then that part of the body will absorb more RF energy. Wireless phones marketed in the U.S. are required to meet safety requirements regardless of whether they are used against the head or against the body. Either configuration should result in compliance with the safety limit.

Do wireless phone accessories that claim to shield the head from RF radiation work?

Since there are no known risks from exposure to RF emissions from wireless phones, there is no reason to believe that accessories that claim to shield the head from those emissions reduce risks. Some products that claim to shield the user from RF absorption use special phone cases, while others involve nothing more than a metallic accessory attached to the phone. Studies have shown that these products generally do not work as advertised. Unlike "hand-free" kits, these so-called "shields" may interfere with

proper operation of the phone. The phone may be forced to boost its power to compensate, leading to an increase in RF absorption. In February 2002, the Federal Trade Commission (FTC) charged two companies that sold devices that claimed to protect wireless phone users from radiation with making false and unsubstantiated claims. According to FTC, these defendants lacked a reasonable basis to substantiate their claim.

What are wireless telephone base stations?

Fixed antennas used for wireless telecommunications are referred to as cellular base stations, cell stations, PCS ("Personal Communications Service") stations or telephone transmission towers. These base stations consist of antennas and electronic equipment. Because the antennas need to be high in the air, they are often located on towers, poles, water tanks, or rooftops. Typical heights for freestanding base station towers are 50-200 feet.

Some base stations use antennas that look like poles, 10 to 15 feet in length, that are referred to as "omni-directional" antennas. These types of antennas are usually found in rural areas. In urban and suburban areas, wireless providers now more commonly use panel or sector antennas for their base stations. These antennas consist of rectangular panels, about 1 by 4 feet in dimension. The antennas are usually arranged in three groups of three antennas each. One antenna in each group is used to transmit signals to wireless phones, and the other two antennas in each group are used to receive signals from wireless phones.

At any base station site, the amount of RF energy produced depends on the number of radio channels (transmitters) per antenna and the power of each transmitter. Typically, 21 channels per antenna sector are available. For a typical cell site using sector antennas, each of the three transmitting antennas could be connected to up to 21 transmitters for a total of 63 transmitters. However, it is unlikely that all of the transmitters would be transmitting at the same time. When omni-directional antennas are used, a cellular base station could theoretically use up to 96 transmitters, but this would be very unusual, and, once again, it is unlikely that all transmitters would be in operation simultaneously. Base stations used for PCS communications generally require fewer transmitters than those used for cellular radio transmissions, since PCS carriers usually have a higher density of base station antenna sites.

Are wireless telephone base stations safe?

The electromagnetic RF signals transmitted from base station antennas stations travel toward the horizon in relatively narrow paths. For example, the radiation pattern for an antenna array mounted on a tower can be likened to a thin pancake centered around the antenna system. The individual pattern for a single array of sector antennas is wedge-shaped, like a piece of pie. As with all forms of electromagnetic energy, the power decreases rapidly as one moves away from the antenna. Therefore, RF exposure on the ground is much less than exposure very close to the antenna and in the path of the transmitted radio signal. In fact, ground-level exposure from such antennas is typically thousands of times less than the exposure levels recommended as safe by expert organizations. So exposure to nearby residents would be well within safety margins.

Cellular and PCS base stations in the United States are required to comply with limits for exposure recommended by expert organizations and endorsed by government agencies responsible for health and safety. Measurements made near cellular and PCS base station antennas mounted on towers have confirmed that ground-level exposures are typically thousands of times less than the exposure limits adopted by the FCC. In fact, in order to be exposed to levels at or near the FCC limits for cellular or PCS frequencies an individual would essentially have to remain in the main transmitted radio signal (at

the height of the antenna) and within a few feet from the antenna. This is, of course, very unlikely to occur.

When cellular and PCS antennas are mounted on rooftops, RF levels on that roof or on others near by would probably be greater than those typically encountered on the ground. However, exposure levels approaching or exceeding safety guidelines should be encountered only very close to or directly in front of the antennas. In addition, for sector-type antennas, typically used for such rooftop base stations, RF levels to the side and in back of these antennas are insignificant. General guidelines on antenna installations and circumstances that might give rise to a concern about an facility's conformance with FCC regulations can be found in *A Local Government Official's Guide to Transmitting Antenna RF Emission Safety: Rules, Procedures, and Practical Guidance*. This Guide can be accessed at: <http://www.fcc.gov/oet/rfsafety>.

Who regulates exposure to radiation from microwave ovens, television sets and computer monitors?

The Food and Drug Administration is responsible for protecting the public from harmful radiation emissions from these consumer products.

Does the FCC routinely monitor radiofrequency radiation from antennas?

The FCC does not have the resources or the personnel to routinely monitor the emissions for all the thousands of transmitters that are subject to FCC jurisdiction. However, the FCC does have measurement instrumentation for evaluating RF levels in areas that may be accessible to the public or to workers. If there is evidence for potential non-compliance with FCC exposure guidelines for a FCC-regulated facility, staff from the FCC's Office of Engineering and Technology or the FCC Enforcement Bureau can conduct and investigation, and, if appropriate, perform actual measurements. Circumstances that could give rise to a concern about an facility's conformance with FCC regulations can be found in in *A Local Government Official's Guide to Transmitting Antenna RF Emission Safety: Rules, Procedures, and Practical Guidance*. This Guide can be accessed at: <http://www.fcc.gov/oet/rfsafety>. Potential exposure problems should be brought to the FCC's attention by contacting the FCC RF Safety Program at: 202-418-2464 or by e-mail: rfsafety@fcc.gov.

Does the FCC maintain a database that includes information on the location and technical parameters of all the transmitting towers it regulates?

Each of the FCC Bureaus maintains its own licensing database system for the service(s) it regulates (e.g., television, cellular service, satellite earth stations.) The FCC issues two types of licenses: site specific and market based. In the case of site specific licensed facilities, technical operating information is collected from the licensee as part of the licensing process. However, in the case of market based licensing (e.g., PCS, cellular), the licensee is granted the authority to operate a radio communications system in a geographic area using as many facilities as are required, and the licensee is not required to provide the FCC with specific location and operating parameters of these facilities.

Information on site specific licensed facilities can be found the "General Menu Reports" (GenMen) at <http://gullfoss2.fcc.gov/cgi-bin/ws.exe/genmen/index.hts>.

The various FCC Bureaus also publish on at least a weekly basis, bulk extracts of their licensing databases. Each licensing database has its own unique file structure. These extracts consist of multiple, very large files. The FCC's Office of Engineering and Technology (OET) maintains an index to these

databases at <http://www.fcc.gov/oet/info/database/fadb.html>. Entry points into the various databases include frequency, state/county, latitude/longitude, call-sign and licensee name. For further information on the Commission's existing databases, you can contact Donald Campbell at dcampbel@fcc.gov or 202-418-2405.

Can local and state governmental bodies establish limits for RF exposure?

Although some local and state governments have enacted rules and regulations about human exposure to RF energy in the past, the Telecommunications Act of 1996 requires the Federal Government to control human exposure to RF emissions. In particular, Section 704 of the Act states that, "No State or local government or instrumentality thereof may regulate the placement, construction, and modification of personal wireless service facilities on the basis of the environmental effects of radio frequency emissions to the extent that such facilities comply with the Commission's regulations concerning such emissions." Further information on federal authority and FCC policy is available in a fact sheet from the FCC's Wireless Telecommunications Bureau at www.fcc.gov/wtb.

Do wireless phones pose a health hazard?

The available scientific evidence does not show that any health problems are associated with using wireless phones. There is no proof, however, that wireless phones are absolutely safe. Wireless phones emit low levels of radiofrequency energy (RF) in the microwave range while being used. They also emit very low levels of RF when in the stand-by mode. Whereas high levels of RF can produce health effects (by heating tissue), exposure to low level RF that does not produce heating effects causes no known adverse health effects. Many studies of low level RF exposures have not found any biological effects. Some studies have suggested that some biological effects may occur, but such findings have not been confirmed by additional research. In some cases, other researchers have had difficulty in reproducing those studies, or in determining the reasons for inconsistent results.

What is FDA's role concerning the safety of wireless phones?

Under the law, FDA does not review the safety of radiation-emitting consumer products such as wireless phones before they can be sold, as it does with new drugs or medical devices. However, the agency has authority to take action if wireless phones are shown to emit radiofrequency energy (RF) at a level that is hazardous to the user. In such a case, FDA could require the manufacturers of wireless phones to notify users of the health hazard and to repair, replace or recall the phones so that the hazard no longer exists.

Although the existing scientific data do not justify FDA regulatory actions, FDA has urged the wireless phone industry to take a number of steps, including the following:

- Support needed research into possible biological effects of RF of the type emitted by wireless phones;
- Design wireless phones in a way that minimizes any RF exposure to the user that is not necessary for device function; and
- Cooperate in providing users of wireless phones with the best possible information on possible effects of wireless phone use on human health

FDA belongs to an interagency working group of the federal agencies that have responsibility for different aspects of RF safety to ensure coordinated efforts at the federal level. The following agencies

belong to this working group:

- National Institute for Occupational Safety and Health
- Environmental Protection Agency
- Federal Communications Commission
- Occupational Safety and Health Administration
- National Telecommunications and Information Administration

The National Institutes of Health participates in some interagency working group activities, as well.

FDA shares regulatory responsibilities for wireless phones with the Federal Communications Commission (FCC). All phones that are sold in the United States must comply with FCC safety guidelines that limit RF exposure. FCC relies on FDA and other health agencies for safety questions about wireless phones.

FCC also regulates the base stations that the wireless phone networks rely upon. While these base stations operate at higher power than do the wireless phones themselves, the RF exposures that people get from these base stations are typically thousands of times lower than those they can get from wireless phones. Base stations are thus not the primary subject of the safety questions discussed in this document.

What kinds of phones are the subject of this update?

The term "wireless phone" refers here to hand-held wireless phones with built-in antennas, often called "cell," "mobile," or "PCS" phones. These types of wireless phones can expose the user to measurable radiofrequency energy (RF) because of the short distance between the phone and the user's head. These RF exposures are limited by Federal Communications Commission safety guidelines that were developed with the advice of FDA and other federal health and safety agencies. When the phone is located at greater distances from the user, the exposure to RF is drastically lower because a person's RF exposure decreases rapidly with increasing distance from the source. The so-called "cordless phones," which have a base unit connected to the telephone wiring in a house, typically operate at far lower power levels, and thus produce RF exposures well within the FCC's compliance limits.

What are the results of the research done already?

The research done thus far has produced conflicting results, and many studies have suffered from flaws in their research methods. Animal experiments investigating the effects of radiofrequency energy (RF) exposures characteristic of wireless phones have yielded conflicting results that often cannot be repeated in other laboratories. A few animal studies, however, have suggested that low levels of RF could accelerate the development of cancer in laboratory animals. However, many of the studies that showed increased tumor development used animals that had been genetically engineered or treated with cancer-causing chemicals so as to be pre-disposed to develop cancer in the absence of RF exposure. Other studies exposed the animals to RF for up to 22 hours per day. These conditions are not similar to the conditions under which people use wireless phones, so we don't know with certainty what the results of such studies mean for human health.

Three large epidemiology studies have been published since December 2000. Between them, the studies investigated any possible association between the use of wireless phones and primary brain cancer, glioma, meningioma, or acoustic neuroma, tumors of the brain or salivary gland, leukemia, or other cancers. None of the studies demonstrated the existence of any harmful health effects from wireless phone RF exposures. However, none of the studies can answer questions about long-term exposures,

since the average period of phone use in these studies was around three years.

What research is needed to decide whether RF exposure from wireless phones poses a health risk?

A combination of laboratory studies and epidemiological studies of people actually using wireless phones would provide some of the data that are needed. Lifetime animal exposure studies could be completed in a few years. However, very large numbers of animals would be needed to provide reliable proof of a cancer promoting effect if one exists. Epidemiological studies can provide data that is directly applicable to human populations, but 10 or more years' follow-up may be needed to provide answers about some health effects, such as cancer. This is because the interval between the time of exposure to a cancer-causing agent and the time tumors develop - if they do - may be many, many years. The interpretation of epidemiological studies is hampered by difficulties in measuring actual RF exposure during day-to-day use of wireless phones. Many factors affect this measurement, such as the angle at which the phone is held, or which model of phone is used.

What is FDA doing to find out more about the possible health effects of wireless phone RF?

FDA is working with the U.S. National Toxicology Program and with groups of investigators around the world to ensure that high priority animal studies are conducted to address important questions about the effects of exposure to radiofrequency energy (RF).

FDA has been a leading participant in the World Health Organization International Electromagnetic Fields (EMF) Project since its inception in 1996. An influential result of this work has been the development of a detailed agenda of research needs that has driven the establishment of new research programs around the world. The Project has also helped develop a series of public information documents on EMF issues.

FDA and the Cellular Telecommunications & Internet Association (CTIA) have a formal Cooperative Research and Development Agreement (CRADA) to do research on wireless phone safety. FDA provides the scientific oversight, obtaining input from experts in government, industry, and academic organizations. CTIA-funded research is conducted through contracts to independent investigators. The initial research will include both laboratory studies and studies of wireless phone users. The CRADA will also include a broad assessment of additional research needs in the context of the latest research developments around the world.

What steps can I take to reduce my exposure to radiofrequency energy from my wireless phone?

If there is a risk from these products--and at this point we do not know that there is--it is probably very small. But if you are concerned about avoiding even potential risks, you can take a few simple steps to minimize your exposure to radiofrequency energy (RF). Since time is a key factor in how much exposure a person receives, reducing the amount of time spent using a wireless phone will reduce RF exposure.

- If you must conduct extended conversations by wireless phone every day, you could place more distance between your body and the source of the RF, since the exposure level drops off dramatically with distance. For example, you could use a headset and carry the wireless phone away from your body or use a wireless phone connected to a remote antenna

Again, the scientific data do not demonstrate that wireless phones are harmful. But if you are concerned about the RF exposure from these products, you can use measures like those described above to reduce

your RF exposure from wireless phone use.

What about children using wireless phones?

The scientific evidence does not show a danger to users of wireless phones, including children and teenagers. If you want to take steps to lower exposure to radiofrequency energy (RF), the measures described above would apply to children and teenagers using wireless phones. Reducing the time of wireless phone use and increasing the distance between the user and the RF source will reduce RF exposure.

Some groups sponsored by other national governments have advised that children be discouraged from using wireless phones at all. For example, the government in the United Kingdom distributed leaflets containing such a recommendation in December 2000. They noted that no evidence exists that using a wireless phone causes brain tumors or other ill effects. Their recommendation to limit wireless phone use by children was strictly precautionary; it was not based on scientific evidence that any health hazard exists.

What about wireless phone interference with medical equipment?

Radiofrequency energy (RF) from wireless phones can interact with some electronic devices. For this reason, FDA helped develop a detailed test method to measure electromagnetic interference (EMI) of implanted cardiac pacemakers and defibrillators from wireless telephones. This test method is now part of a standard sponsored by the Association for the Advancement of Medical Instrumentation (AAMI). The final draft, a joint effort by FDA, medical device manufacturers, and many other groups, was completed in late 2000. This standard will allow manufacturers to ensure that cardiac pacemakers and defibrillators are safe from wireless phone EMI.

FDA has tested hearing aids for interference from handheld wireless phones and helped develop a voluntary standard sponsored by the Institute of Electrical and Electronic Engineers (IEEE). This standard specifies test methods and performance requirements for hearing aids and wireless phones so that no interference occurs when a person uses a "compatible" phone and a "compatible" hearing aid at the same time. This standard was approved by the IEEE in 2000.

FDA continues to monitor the use of wireless phones for possible interactions with other medical devices. Should harmful interference be found to occur, FDA will conduct testing to assess the interference and work to resolve the problem.

Which other federal agencies have responsibilities related to potential RF health effects?

Certain agencies in the Federal Government have been involved in monitoring, researching or regulating issues related to human exposure to RF radiation. These agencies include the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), the National Institute for Occupational Safety and Health (NIOSH), the National Telecommunications and Information Administration (NTIA) and the Department of Defense (DOD).

By authority of the Radiation Control for Health and Safety Act of 1968, the Center for Devices and Radiological Health (CDRH) of the FDA develops performance standards for the emission of radiation from electronic products including X-ray equipment, other medical devices, television sets, microwave ovens, laser products and sunlamps. The CDRH established a product performance standard for

microwave ovens in 1971 limiting the amount of RF leakage from ovens. However, the CDRH has not adopted performance standards for other RF-emitting products. The FDA is, however, the lead federal health agency in monitoring the latest research developments and advising other agencies with respect to the safety of RF-emitting products used by the public, such as cellular and PCS phones.

The FDA's microwave oven standard is an emission standard (as opposed to an exposure standard) that allows specific levels of microwave leakage (measured at five centimeters from the oven surface). The standard also requires ovens to have two independent interlock systems that prevent the oven from generating microwaves the moment that the latch is released or the door of the oven is opened. The FDA has stated that ovens that meet its standards and are used according to the manufacturer's recommendations are safe for consumer and industrial use. More information is available from: www.fda.gov/cdrh.

The EPA has, in the past, considered developing federal guidelines for public exposure to RF radiation. However, EPA activities related to RF safety and health are presently limited to advisory functions. For example, the EPA now chairs an Inter-agency Radiofrequency Working Group, which coordinates RF health-related activities among the various federal agencies with health or regulatory responsibilities in this area.

OSHA is responsible for protecting workers from exposure to hazardous chemical and physical agents. In 1971, OSHA issued a protection guide for exposure of workers to RF radiation [29 CFR 1910.97]. However, this guide was later ruled to be only advisory and not mandatory. Moreover, it was based on an earlier RF exposure standard that has now been revised. At the present time, OSHA uses the IEEE and/or FCC exposure guidelines for enforcement purposes under OSHA's "general duty clause" (for more information see: <http://www.osha-slc.gov/SLTC/radiofrequencyradiation/index.html>)

NIOSH is part of the U.S. Department of Health and Human Services. It conducts research and investigations into issues related to occupational exposure to chemical and physical agents. NIOSH has, in the past, undertaken to develop RF exposure guidelines for workers, but final guidelines were never adopted by the agency. NIOSH conducts safety-related RF studies through its Physical Agents Effects Branch in Cincinnati, Ohio.

The NTIA is an agency of the U.S. Department of Commerce and is responsible for authorizing Federal Government use of the RF electromagnetic spectrum. Like the FCC, the NTIA also has NEPA responsibilities and has considered adopting guidelines for evaluating RF exposure from U.S. Government transmitters such as radar and military facilities.

The Department of Defense (DOD) has conducted research on the biological effects of RF energy for a number of years. This research is now conducted primarily at the U.S. Air Force Research Laboratory located at Brooks Air Force Base, Texas. The DOD Web site for RF biological effects information is listed with other sites in conjunction with a question on other sources of information, below.

Who funds and carries out research on the biological effects of RF energy?

Research into possible biological effects of RF energy is carried out in laboratories in the United States and around the world. In the U.S., most research has been funded by the Department of Defense, due to the extensive military use of RF equipment such as radar and high-powered radio transmitters. In addition, some federal agencies responsible for health and safety, such as the Environmental Protection Agency (EPA) and the U.S. Food and Drug Administration (FDA), have sponsored and conducted research in this area. At the present time, most of the non-military research on biological effects of RF energy in the U.S. is being funded by industry organizations. More research is being carried out

overseas, particularly in Europe.

In 1996, the World Health Organization (WHO) established the International EMF Project to review the scientific literature and work towards resolution of health concerns over the use of RF technology. WHO maintains a Web site that provides extensive information on this project and about RF biological effects and research (www.who.ch/peh-emf).

FDA, EPA and other US government agencies responsible for public health and safety have worked together and in connection with WHO to monitor developments and identify research needs related to RF biological effects.

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