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Health informatics — Use of mobile wireless communication and computing technology in healthcare facilities — Recommendations for the management of unintentional electromagnetic interference with medical devices

Informatique de santé — Utilisation de communications mobiles sans fil et des technologies informatisées dans les structures de soins — Recommandations pour la gestion des interférences électromagnétiques non intentionnelles avec les dispositifs médicaux

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Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TR 21730 was prepared by Technical Committee ISO/TC 215, *Health Informatics*, Task Force on EMC in RF mobile communications.

Other international organizations that contributed to the preparation of this Technical Report, mainly in review and comment of draft text, include, from the UK the MHRA and the IST/35 Mirror Panel, from the US the FDA, from Australia the Australian Therapeutic Goods Administration, Telstra, and Monash Medical Center, from Canada Health Canada Medical Devices Bureau, from the Netherlands the Health Council of the Netherlands, from Finland the National Agency for Medicines, and from Switzerland Swissmedic.

Due to rapidly changing technologies, this report must be regarded as a "living document" and comments for improvement will therefore be welcomed.

The current Technical Report strongly parallels the AAMI TIR #18, which provides similar recommendations for wireless equipment in healthcare facilities.

Introduction

There is a growing need in healthcare facilities throughout the world to incorporate new technology to offer more efficient, cost-effective and higher quality healthcare. In that regard, wireless communication and computing technologies have the potential to offer significant advancements to healthcare communication and health informatics exchange. Such wireless technologies include the use of mobile phones, handheld computers/PDAs, WiFi/802.11.a/b/g local area networks and wireless modems for laptop computers, personal area networks including 802.15.1 (Bluetooth)/802.15.4 (Zigbee)/802.15.3a (UWB), two-way pagers, radios, etc. In addition, visitors and patients are also finding use of personal mobile phones and other wireless devices within healthcare facilities increasingly indispensable, especially in times of crisis.

Currently, no uniform international guideline exists for the appropriate deployment, use, and management of mobile wireless communication and computing technology within healthcare facilities to mitigate potential electromagnetic interference (EMI) with sensitive medical devices. Although medical device manufacturers generally comply with recommended immunity guidelines (10 V/m for life-critical devices as outlined in the recently approved second edition of the IEC International Standard 60601-1-2), there is no consistent international regulation enforcing this recommendation. In addition, many mobile wireless transmitters exceed this field strength threshold when operating at their upper power limits and in close proximity. Finally, there are a number of older medical devices still in circulation that have not been designed with the above immunity considerations in mind.

Misinformation regarding mobile wireless systems, electromagnetic interference, and management procedures has led to a range of inconsistent policies among healthcare organizations. At one extreme, overly-restrictive policies may act as obstacles to beneficial technology as well as not address the growing personal communication needs of patients, visitors, and the workforce. At the other extreme, unmanaged use can place patients at risk. An equally important factor in this issue is that healthcare organizations throughout the world have a variety of different resources, needs, concerns, and RF environments that may not all be addressed by implementation of a single prescriptive management strategy. Because of this, a balanced approach is necessary to ensure that all the benefits of mobile wireless technology can be made available to healthcare organizations that desire to fully implement comprehensive management procedures, while sufficient safeguards are offered to organizations where these same comprehensive management procedures cannot be, or otherwise have not been, fully implemented.

It may not be feasible for healthcare organizations to manage every mobile wireless handset brought into their facility without certain restrictive limits. The necessary range and extent of restrictive limits within a given healthcare facility will depend upon the level of management that has been implemented. For mobile wireless equipment that is randomly brought into the healthcare facility in an uncontrolled manner, policies restricting use in sensitive areas where life-critical medical devices are in routine operation may be appropriate. Such restrictive policies might be facilitated by offering numerous and easily accessible alternative areas where the use of mobile wireless equipment is encouraged. For mobile wireless equipment that is provided to doctors and staff under more controlled conditions, operation throughout the healthcare facility (even in sensitive areas) may be achievable with appropriate management. With such management, as outlined in the recommendations below, it is possible to realize many of the benefits of wireless technology for healthcare-specific communication and health information access while at the same time sufficiently mitigating EMI concerns.

Because most mobile wireless communication and computing systems can be effectively managed to mitigate EMI issues, the choice of technology for a controlled system should be based upon which solution best addresses the needs of the organization, not on what RF signal types may be inherently more or less prone to EMI under unmanaged conditions.

Health informatics — Use of mobile wireless communication and computing technology in healthcare facilities — Recommendations for the management of unintentional electromagnetic interference with medical devices

1 Scope

This International Standard provides guidance for the deployment, use and management of mobile wireless communication and computing equipment in the healthcare facility in a way that helps mitigate potential hazards due to electromagnetic interference (EMI) with medical devices. The recommendations recognize the different resources, needs, concerns and environments of healthcare organizations around the world and provide detailed management guidelines for healthcare organizations that desire full deployment of mobile wireless communication and computing technology throughout their facility, as well as selective restrictions for healthcare organizations that have decided comprehensive management procedures are not feasible, practical, or desirable at the present time. The recommendations also distinguish between controlled systems used by doctors and staff for healthcare-specific communication and health informatics transport vs. non-controlled (personal) mobile wireless equipment randomly brought into the facility by visitors, patients, and the healthcare organization workforce.

2 Terms, definitions and abbreviated terms

2.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1.1
hertz
Hz
unit of frequency of electromagnetic energy based upon the emitted wavelength

2.1.2
decibel
dB
a relative ratio, one tenth of the common logarithm of the ratio of relative powers, equal to 0,1 B (bel)

NOTE The ratio in dB is given by $dB = 10\log_{10}(P_1/P_2)$.

2.1.3
decibel
dBm
decibels as above, but relative to a fixed 1 milliwatt of power

2.2 Abbreviated terms

AAMI	Association for the Advancement of Medical Instrumentation
AHA	American Hospital Association
AMA	American Medical Association
AMPS	Advanced Mobile Phone System
ANSI	American National Standards Institute
ASHE	American Society for Healthcare Engineering
CDMA	Code Division Multiple Access
CDRH	Center for Devices and Radiological Health, Department within FDA (United States)
CISPR	International Special Committee on Radio Interference
COMAR	IEEE Committee on Man and Radiation
DECT	Digitally Enhanced Cordless Telecommunications
ECG	Electrocardiogram
EEG	Electroencephalogram
EMC	Electromagnetic Compatibility
EMI	Electromagnetic Interference
ESD	Electrostatic Discharge
FDA	Food and Drug Administration (United States)
FOMA	Freedom of Mobile Multimedia Access
GPRS	General Packet Radio Service
GSM	Global System for Mobile
iDEN	Integrated Dispatch Enhanced Network
IEC	International Electrotechnical Commission
IEEE	Institute for Electrical and Electronics Engineers
ISM	Industry, Science and Medicine
ITU	International Telecommunication Union
IVDs	In Vitro Diagnostic Devices
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
JTACS	Japanese Total Access Communications System
LAN	Local Area Network, including 802.11b and 802.11a systems
LMR	Land Mobile Radio
MHRA	Medicines and Healthcare Products Regulatory Agency (United Kingdom)
NADC	North American Digital Cellular
PAN	Personal Area Network, including 802.15.1 (Bluetooth), 802.15.4 (Zigbee), 802.15.3a, etc.
PDA	Personal Digital Assistant

PDC	Personal Digital Cellular
PCS	Personal Communications Services
R&TTE	Radio and Telecommunications Terminal Equipment
RF	Radiofrequency, classically defined as ranging from a few KHz – 300 GHz
Rx	Reception, received RF signal
TACS	Total Access Communications System
TDMA	Time Division Multiple Access
TIR	Technical informational Report
Tx	Transmission, transmitted RF signal
UMTS	Universal Mobile Telecommunications Systems
V/m	Volts per metre, a measure of RF electrical field strength
VoIP	Voice-over Internet Protocol
WAN	Wide Area Network
WAP	Wireless Application Protocol
WCDMA	Wide band Code Division Multiple Access
WiFi	Wireless Fidelity network system

3 Requirements

3.1 Mobile wireless equipment in healthcare facilities

The use of mobile wireless equipment by doctors and healthcare staff for improved healthcare communication and computing is becoming increasingly common. Visitors and patients are likewise finding the use of personal mobile phones and wireless devices within healthcare facilities increasingly indispensable, especially in times of crisis. Such wireless devices might include mobile phones, handheld computers / PDAs, WiFi / 802.11.a/b/g [1] local area networks and wireless modems for laptop computers, personal area networks including 802.15.1 (Bluetooth) [2] / 802.15.4 (Zigbee) [3] / 802.15.3a (UWB), two-way pagers, radios, etc.

Table 1 lists many of the common wireless technologies in use in various healthcare facilities. As can be seen from Table 1, mobile wireless equipment can transmit on exclusive licensed frequencies, as is the case with most mobile phones, pagers, and two-way radios, or can operate with many other transmitters on one of the unlicensed Industry, Science, and Medicine (ISM) bands at 900 MHz and 2,4, 5,2, and 5,8 GHz as is the case with cordless phones and wireless data network equipment. From a radiofrequency (RF) signal perspective, mobile wireless transmitters can employ either simple analogue or more complex (and sometimes pulse modulated) digital technology. In terms of output power, mobile wireless equipment can be segmented into three broad categories. The first category includes 802.11, 802.15, and most cordless phone-type systems that transmit constantly at relatively lower power ($\leqslant$ 10 milliwatts). A second category consists of two-way radio and pager systems that transmit at a constant power that is higher by an order of magnitude of more than 1 to 5 watts. The third category includes dynamically power-controlled equipment that can transmit at levels from a few milliwatts to 1 to 2 watts based upon the existing network signal strength at that particular location and time.

An immediate benefit to healthcare that improved mobile wireless communication and computing may provide is underscored by a U.S. Institute of Medicine (IOM) report estimating that common medical errors, many of which may be avoided with better communication and computing links, contribute to between 44 000 and 98 000 deaths per year in the United States [4]. A similar percentage was also suggested for the

United Kingdom and Australia. Other potential healthcare benefits that wireless technology might provide include immediate communication and access to patient information, test results, records and medical reference at the point-of-care, as well as reduction in cost charging errors, reduction in cost and maintenance of land-line phone systems, and ultimately facilitation of more home-based monitoring, recovery, and long-term care.

Concern over potential EMI with medical devices due to RF emissions, however, has prompted many healthcare organizations around the world to enact broad precautionary policies restricting wireless equipment throughout their facilities. Other healthcare organizations have implemented policies ranging from selective restrictions on where mobile wireless equipment can operate to relatively unrestricted and unmanaged use. While overly restrictive policies may act as obstacles limiting the benefit that wireless technology can bring to healthcare, unmanaged use may expose patients to potentially significant and unnecessary hazards.

Table 1 — Geographical region of use, transmitted frequency and expected output power for common wireless technologies used in healthcare facilities

Type of device			Intended application	Transmitted frequency	Maximum transmit power
Wireless data network devices	W-LAN (Local Area Networks — WiFi)	802.11a	High Rate Local Area Network	5,15–5,8 GHz	40 mW [5,15–5,25 GHz] 200 mW [5,25–5,35 GHz] 800 mW [5,72–5,82 GHz]
		802.11b	Medium Rate Local Area Network	2,4-2,462 GHz (North America), 2,412-2,472 GHz (Europe), 2,471-2,497 GHz (Japan)	**typical app's**: constant ~10 mW, but spec allows for: 1 W [US] 100 mW [Europe] 10 mW/MHz [Japan]
		802.11g	High Rate Local Area Network	2,4–2,48 GHz (US, Europe, Japan)	**typical app's**: constant ~10 mW, but spec allows for: 1 W [US], 100 mW [Europe], 10 mW/MHz [Japan]
	W-PAN (Personal Area Networks)	Bluetooth / 802.15.1	Streaming Data, Cable Replacement	2,4-2,48 GHz (North America & Europe), 2,447-2,473 GHz (Spain), 2,448-2,482 GHz (France), 2,473-2,495 GHz (Japan)	Powerclass I: 100 mW Powerclass II: 2,5-10 mW Powerclass III: 1 mW
		802.15.3a	Streaming Video, Data and Voice	UWB in 3 to 10 GHz band	~0,6 mW spread over 100's of MHz
		Zigbee / 802.15.4	Sensor Networks, Low-Latency Data/Control	2,4-2,48 GHz (North America & Europe), 2,412-2,472 GHz (Europe), 2,471-2,497 GHz (Japan)	**typical app's**: constant ~1 mW, but spec allows for: 1 W [US], 100 mW [Europe], 10 mW/MHz [Japan]
	W-MAN (Metropolitan Area Networks)	802.16a (fixed)	Fixed Broadband Wireless Access Systems (Video + simultaneous voice & data)	2-11 GHz in unlicensed (e.g. 5,8 GHz) and licensed (e.g. 10,5, 25, 26, 31, 38 and 39 GHz) bands	
		802.16e (mobile)	Mobile (UNLICENSED & licensed) Broadband Wireless Access Systems (Video + simultaneous voice & data)	2-11 GHz in unlicensed (e.g. 5,8 GHz) and licensed (e.g. 10,5, 25, 26, 31, 38 and 39 GHz) bands	
		802.20	Mobile (LICENSED) Broadband Wireless Access Systems (Video + simultaneous voice & data)	licensed bands below 3,5 GHz	

Table 1 (*continued*)

Type of device			Intended application	Transmitted frequency	Maximum transmit power
Wired Network		*802.3*	*Hard Line Ethernet*	*(hard line)*	
Mobile Phones	1st Generation Technologies	Analogue	WAN Mobile Communication	AMPS 824-849 MHz (US), NMT 453-458 MHz (Europe), TACS 890-915 MHz (Europe), JTACS 832-925 MHz (Japan)	**AVG PWR**: 0,6-1 watt down to ~6 mW in steps of -4dB
	2nd Generation (Digital) Technologies	TDMA	WAN Mobile Communication	GSM 824-849 & 1850-1910 MHz (US), GSM 890-915 & 1710-1785 MHz (Europe, Asia), iDEN 806-824 MHz (US), Tetra 380-400, 410-430, 450-470 & 805-870 MHz (Europe), PDC 810-826 & 1429-1453 MHz (Japan)	**AVG PWR**: 200-600 mW down to 20-2 mW in steps of -1 to -4 dB
		CDMA	WAN Mobile Communication	CDMA 824-849 & 1850-1910 MHz (US), J-CDMA 832-925 MHz (Japan), K-PCS 1750-1870 MHz (Korea)	**AVG PWR**: 250 mW to ≂1 uW in 1dB steps
	3rd Generation (IMT-2000) Technologies	UMTS	WAN Mobile Communication	1,92-1,98 MHz (Europe,Asia), 1,7-2 GHz (US)	**AVG PWR**: 250 mW to ⩽ 1 mW in steps of 0,25-1 dB
		CDMA-2000	WAN Mobile Communication	824-849, 1850-1910 MHz & 1,7-2 GHz (US); 890-915 & 1750-1780 MHz & 1,92-1,98 GHz (Europe, Asia)	**AVG PWR**: 250 mW to ⩽ 1 mW in steps of 0,25-1 dB
2-way pagers			WAN Text Messaging	152-159, 454-460, 902-928 MHz	1 W (in short bursts)
Cordless Phones		Analogue and Spread Spectrum Technologies		Analogue 27, 40-49, 900 MHz & 2,4, 5,8 GHz (US), Spectralink 2,4 GHz (US, Europe), CT-1 30-41, 72,8-73, 885, 914, 960 MHz & 1,7-1,8 GHz (Europe)	**AVG PWR**: constant 10 mW, some units up to 1 W
		TDMA		DECT 1880-1900 MHz (Europe), CT2, CT3 864-868 & 944-948 MHz (Europe), PHS 1895-1918 (Japan)	**AVG PWR**: constant 10 mW, **PEAK PWR**: constant 250 mW
		VoIP / 802.11b	LAN Mobile Communication	2,4-2,462 GHz	**AVG PWR**: constant 10 mW
Short Range Devices		FCC 15.231, FCC 15.249	Low-Power Radio Links	Periodic and continuous transmissions, 300-900, 2400, 5800 MHz	**AVG PWR**: 0,1 to 1 mW
		ETSI 300 220-1	Low-Power Radio Links	Periodic and continuous transmissions, 400 and 800 MHz	**AVG PWR**: 10 to 25 mW
		JPN ARIB T-67	Low-Power Radio Links	Periodic and continuous transmissions, 426-449 MHz	**AVG PWR**: 1 and 10 mW

3.2 The risk of patient harm due to EMI

The uncontrolled use of mobile wireless equipment by individuals visiting and working in healthcare facilities has steadily increased, regardless of existing healthcare organization policy. However, the level of risk for accidental EMI events from government and other non-profit health agency sources appears to be relatively small [5]-[7], although underreporting of such events may be substantial. Anecdotal observations of suspected EMI incidents with ECG and EEG machines, apnea monitors, ventilators and radiant warmers, infusion pumps, wheelchairs, and other devices have been reported or referred to in a number of publications [5]-[18]. Ad hoc test studies [19]-[30], [44] have confirmed that interference effects can be precipitated by certain wireless

transmitters in susceptible medical devices, although this generally requires extreme conditions (transmission at higher power levels, close proximity, for extended periods of time) that may not be common during normal use. In RF transmitters that operate at constant output power of 100 milliwatts or less, significant interference effects were not observed [45], [46].

Although medical device manufacturers generally comply with a 10-V/m immunity level against interference from relevant RF emissions in the design of new life-critical devices, many mobile wireless handsets exceed the 10-V/m limit when operating at maximal power and in close proximity. In addition, this immunity level is only recommended in some countries and may be waived with appropriate exemptions. Further, many older medical devices still in use may not have been constructed to the same immunity level. Despite this apparently uncommon but potentially serious level of risk due to unmanaged mobile wireless handset use, most mobile wireless equipment can operate in a fully compatible manner throughout a healthcare facility, even where potentially sensitive medical devices are used, if comprehensive management procedures are implemented.

3.3 Existing relevant standards and recommendations

IEC has published a standard (IEC 60601-1-2) [32] recommending that “all life-supporting medical electrical equipment and systems be immune to field strengths of 10 V/m” and “medical electrical equipment and systems that are not life-supporting be immune to field strengths of 3 V/m in the frequency range 80 MHz to 2,5 GHz”. This is the collateral to the general safety standard for medical electrical equipment (IEC 60601-1) [30], based upon basic EMC immunity standards that were developed by IEC Technical Committee (TC) 77 (EMC). IEC 60601-1-2 also sets limits for emissions and immunity test levels for electrostatic discharge (ESD), conducted radiofrequency electromagnetic fields, bursts and surges largely based upon CISPR emissions and TC 77 immunity standards. Although many medical device manufacturers comply with recommended immunity guidelines, there is no government regulation enforcing these recommendations in certain parts of the world, including the United States. Further, many older medical devices still in use in healthcare facilities were not designed or tested to the current immunity levels. Also, the IEC standard permits medical equipment and systems to meet lower immunity levels, with appropriate justification [32], and 60601-1-2 Annex AAA states “ It is expected that some PATIENT-COUPLED EQUIPMENT and SYSTEMS will use as a justification for a lower IMMUNITY COMPLIANCE LEVEL the fact that some physiological signals can be substantially below those induced by a field strength of 3 V/m”.

The European Community has issued a set of medical device directives to further ensure compliance with electromagnetic immunity for devices operating in Europe. Directive 93/42/EEC [34] specifies immunity requirements for external medical devices based upon an EMI risk classification scheme of low, medium, and high. Article 2(a) of this directive incorporates, as an integral part, or as an accessory: (a) a medical device within the meaning of Article 1 of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (15), or (b) an active implantable medical device within the meaning of Article 1 of Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (16), the apparatus shall be governed by this Directive, without prejudice to the application of Directives 93/42/EEC and 90/385/EEC to medical devices and active implantable medical devices, respectively. The horizontal (general) directive [35] regarding medical device safety also applies. Other relevant directives include immunity requirements for active implantable devices [36], in vitro diagnostic devices (IVDs) [37], and medicinal products [38]. A recent Radio and Telecommunications Terminal Equipment (R&TTE) Directive [39] now specifies testing protocols and RF immunity levels for radio and telecommunications terminal equipment within the European Union. Included within the scope of the R&TTE directive is that if the radio and telecommunications terminal equipment incorporates an external [34] or active implantable [36] medical device, that apparatus is to be governed by the R&TTE directive. The purpose is to allow radio and telecommunications terminal equipment manufacturers to follow the same rules for medical devices but bring their products to the European market faster and more easily. While the additional directives in Europe do encourage medical devices to meet the IEC standard, many mobile wireless transmitters operating at full power can exceed the 10 V/m immunity level at distances up to 1 m [10]-[12], [20]-[23].

ANSI has published a rapid, cost-effective, and straightforward ad hoc test protocol [40] that can be implemented by individual healthcare organizations to assess EMI with medical devices in their inventory that can be caused by the transmission of specific mobile wireless signals. The protocol not only allows individual healthcare organizations to rapidly generate information to make more informed policies on wireless

equipment access in their facility, but also provides a consistent protocol allowing comparison of findings between different test sites.

A TIR published by the AAMI [10] is currently the most useful guideline available to healthcare organizations in defining EMI in simple terms for non-engineering healthcare facility staff and describing how potentially significant medical device EMI can occur and how the risk can be managed. The document follows closely from earlier studies performed by ASHE [15], [16] and provides information on assessing and managing the RF environment and a model EMC/EMI policy. The summary recommendations of AAMI TIR 18 are currently listed on the FDA CDRH website [41]. Previously, the FDA CDRH had developed a set of voluntary guidelines [42] for manufacturers to test respiratory and anaesthesiology devices.

The IEEE Committee on Man and Radiation (COMAR) of the Engineering in Medicine and Biology Society has published a manuscript stating that EMI of critical life-support equipment due to emissions from mobile telephones is a valid concern and steps should be taken by medical device manufacturers to "harden" their devices against increasing environmental RF fields [24], although limited guidance to healthcare organizations on how to manage the risk is provided.

The AMA identifies the operation of mobile wireless equipment in healthcare facilities as a risk to medical equipment [4] especially when used in close proximity. Its published paper acknowledges that current clinical reports of EMI are uncommon and largely anecdotal suggesting that the risk may be small, and that the variety of communication signal and medical equipment types make EMI difficult to predict. It recommends obtaining (when possible) newer medical equipment "hardened" to extraneous RF emissions, performing ad hoc testing per the ANSI/IEEE C63.18 protocol, applying straight-forward management procedures, maintaining compliance with existing EMC standards, and ongoing vigilance against EMI by the clinical engineering group and medical staff at the healthcare facility. It does not recommend precautionary banning of wireless devices, but recommend a general (1 m) separation distance as per the revised ECRI 1999 recommendations [11].

The Oklahoma University EMC Center [43] released a manual in 1998 for healthcare facilities. With regard to specific recommendations, a significant source of this information was taken (with permission) from Segal [31]. The recommendations promote ad hoc testing and education, and suggest various management procedures including the establishment of a comprehensive EMC policy, establishment of mobile handset exclusion zones and EMI reporting procedures, and replacing and/or increasing immunity of medical devices whenever possible. The manual also suggests maintaining separation distances (up to 6 m for standard radios, 2 m for common mobile phones, 0,3 m for in-building LAN and cordless phone systems).

Health Canada's Medical Devices Bureau has performed extensive ad hoc testing of RF transmitters including mobile phones, 802.11b LAN, electronic article surveillance systems, metal detectors, and 802.15.1 bluetooth transmitters [44]-[46] and reported that while mobile phones and radios may cause interference if their use is not properly managed, the majority of constant output low power transmitters do not pose significant threats to medical devices under normal operating conditions. The Medical Devices Bureau also hosted a roundtable discussion [47] in 1994 to develop recommendations and define a U.S.-Canadian Task Force on Electromagnetic Compatibility in Health Care, with Dr. Bernard Segal of McGill University acting as coordinator. Summary recommendations included promotion of the use of wireless technology in healthcare, coupled with testing and encouraging hospital clinical engineering groups to become proactive in the characterization and management of potential EMI issues in their facilities. Suggested activities included management of medical devices, lowering power of RF transmitters, labelling susceptible devices, educating staff, and upgrading where possible and practical with hardened medical equipment purchases.

The Health Council of the Netherlands [48] recommends a precautionary separation distance of 1,5 m, although it states that it is "unaware of an actual case in which a mobile phone has led to interference with sensitive medical equipment" and does not directly advocate comprehensive precautionary bans. The report states that most healthcare facilities in the Netherlands currently apply blanket bans on wireless communication devices largely as a precautionary measure.

The MHRA (formerly the MDA) in the United Kingdom recommends the use of GSM and TETRA mobile phone handsets on healthcare facility premises follow local healthcare facility policy guidelines [49]. It further recommends that on-site interference due to operation of emergency services radios be treated as secondary to the risks associated with managing the incident.

The AHA and its affiliated group ASHE published its recommendations in the previously mentioned documents on the subject [15], [16] and are advocates of managed use in the healthcare facility. JCAHO has no specific recommendation, but when performing accreditation reviews it does check to see that healthcare facilities are implementing their own EMC management plan, whatever it may be.

The U.S. Army Center for Health Promotion and Preventative Medicine recommends maintaining new medical device inventories, EMC education, appropriate signage guidance and EMI reporting, and restricting all personal wireless equipment in critical care areas [50]. The recommendations also suggest limiting wireless equipment in ER unless it is critical for medical treatment and separated by more than 3,3 ft from medical devices.

Although not discussed in detail in this review, medical device EMI can be caused by RF sources other than mobile wireless equipment, and in particular from other neighbouring medical devices. Emission limits for industrial, scientific, and medical (ISM) equipment are specified by International Special Committee on Radio Interference standard CISPR 11 [51]. This standard specifies limits and methods for measuring electromagnetic emissions from ISM equipment in the frequency range 150 kHz to 18 GHz, as well as frequencies at which emissions are unlimited. In particular, consideration of radiated emissions is given to medical devices complying with European Medical Devices or the Active Implantable Medical Devices directives, and they are therefore not likely candidates for interference with other equipment.

3.4 Minimization of EMI risk

Certainly, one goal of the current recommendation is to urge medical device manufacturers to increase the electromagnetic immunity levels of their medical devices as the healthcare facility environments they operate in become increasingly permeated with radiofrequency emissions from a variety of sources. It should be urged that manufacturers strive to exceed current IEC requirements of 3 and 10 V/m, as these fields can be exceeded by many types of mobile wireless transmitters operating at the higher transmit power steps and in close proximity.

An equally important goal of the following recommendation is to provide sufficient guidance to allow healthcare organizations to achieve the benefits of mobile wireless technology while at the same time appropriately managing EMI issues to mitigate risk. Controlled systems to be used by healthcare facility staff may include handsets operating on peer-to-peer (radio), local area (cordless phone, WiFi / 802.11b / LAN system), or wide area (mobile phone, pager, PDA) networks. The following recommendations provide for the management of many types of mobile wireless systems, allowing the choice of technology that best addresses the communication and/or computing needs of the healthcare facility to be implemented through proper testing, system design & engineering, medical device management, and user guidelines.

In contrast to controlled handsets, a different set of recommendations is necessary to avoid medical device interference that might be caused by the use of mobile wireless transmitters inside healthcare facilities under uncontrolled conditions. For example, while it may be entirely possible to implement a management strategy for a controlled mobile wireless system used by healthcare staff, it may be impractical in many cases to ensure the same level of management for non-controlled wireless handsets brought into the healthcare facility by visitors, patients or the workforce. Further, many healthcare organizations may decide that management procedures for controlled mobile wireless systems are not feasible, practical or desirable. When such is the case, an approach characterized by certain restrictions for use in sensitive areas, especially those areas with a high concentration of life-support medical devices in operation, may be appropriate.

4 Recommendations

4.1 General recommendations

Important recommendations are made equally to medical device manufacturers, healthcare facilities, and wireless equipment manufacturers.

For medical device manufacturers, they should continue to meet and exceed current IEC 60601-1-2 listed electromagnetic immunity levels in the design of new medical equipment which will increasingly operate in environments where emissions from RF transmitters are common.

For healthcare facilities, they should manage wireless equipment within their facility in accordance with the following guidelines, and neither unduly limit the use of otherwise beneficial technology or ignore the potential for EMI issues.

For wireless equipment manufacturers, they should have full understanding of the potential EMI issues that can arise in worst case scenarios with medical devices as well as other wireless equipment, and deploy their equipment and systems appropriately in accordance with the following recommendations.

4.2 Responsibility within healthcare facilities

Within the healthcare facility, clinical/biomedical engineers should be the focal point for EMC, EMI mitigation, and EMC/EMI education and training. Qualifications are not specified in this document, although consideration should be given to appropriate education, expertise, and experience of the responsible individuals

4.3 Inventory within healthcare facilities

The medical device inventory within a healthcare facility should be managed to the extent possible and practical to ensure compatibility with the everincreasing RF environment.

a) In the purchase of new medical devices by healthcare facilities, every effort should be made to ensure the equipment meets (and exceeds if possible) minimum immunity requirements set out by IEC 60601-1-2. Older equipment found to be particularly susceptible to EMI from mobile wireless transmitters should be phased out as is possible and practical within the healthcare facility budget.

b) While permanent modifications to medical devices should not be made by healthcare facilities, certain simple precautions can be taken to reduce the risk of EMI from mobile wireless transmitters. EMI susceptibility in all medical devices can be reduced by positioning cables, sensors, and electrical accessories in such a way as to increase the distance between these components and RF transmitters operating in the area. Life-critical medical devices or those known or suspected of being susceptible to EMI can be positioned away from high traffic areas or adjoining rooms where mobile wireless equipment may be in routine operation.

4.4 Testing within healthcare facilities

Comprehensive ad hoc, on-site testing of all mobile wireless equipment that might be used in the healthcare facility by staff, visitors, or patients to characterize potential EMI issues with medical devices should be considered whenever possible. However, exhaustive testing is rarely feasible, and it is understood that testing of any nature may not always be possible or practical due to budget, time, and personnel constraints of the healthcare facility. Because of this, the following suggestions are provided:

a) The **IEEE / ANSI C63.18** recommended practice is the suggested test protocol for rapid and practical ad hoc, on-site RF EMI testing.

b) If comprehensive testing of all mobile wireless equipment is not possible, focused testing on higher powered equipment transmitting at constant output (specifically two-way radios) as well as dynamically power controlled equipment (specifically mobile phones) is more crucial than testing equipment such as 802.11, 802.15, and cordless phone-type systems that constantly transmit at power levels of 10-100 milliwatts. A description of lower power, higher power, and dynamically controlled wireless equipment is outlined in more detail in Clause 3 (above).

c) If testing of mobile wireless equipment is not possible, some information may also be available from other groups by accessing the ad hoc EMI testing database at www.ASHE.com.

d) A record of EMI issues and ad hoc testing should be kept by the healthcare facility for forward reference.

4.5 Controlled use within healthcare facilities

For controlled mobile wireless equipment to be used by physicians and healthcare organization staff under managed conditions:

a) It is recommended that appropriate on-site ad hoc testing be performed on one or two representative unit(s) of life-critical medical devices in the equipment inventory using one of the mobile handsets as a test transmitter to characterize any potential EMI issues. For mobile wireless equipment having a constant power output of 10 mW or less (such as equipment operating on 802.11a/b/g LAN or 802.15 PAN networks), the risk of EMI is significantly less than for equipment with maximal power outputs between a few hundred milliwatts to 1 watt or greater (mobile phones, two-way radios, PDAs operating on wide area networks, etc.). While it is always recommended to perform testing whenever possible with all mobile wireless systems, it is understood that considerations of feasibility and practicality must be considered. As an alternative, some information might be obtained either from the manufacturer or by comparison with similar ad hoc on-site testing results in a database available at www.ashe.com.

   1) The **IEEE / ANSI C63.18** recommended practice is the suggested test protocol for rapid and practical ad hoc, on-site RF EMI testing.

   2) Testing should take special consideration of older medical devices, life-supporting medical devices, and any device where EMI is suspected. Testing can be extended to other medical devices where feasible and practical. See C63.18 for a recommended prioritization.

   3) Testing should be performed using one of the mobile wireless handsets to be used in the controlled system as a test transmitter. If multiple in-house systems are to be deployed, testing should be performed with each different RF signal type. If new in-house systems are deployed, each different RF signal type should be tested. Different EMI effects can be caused by different RF signal types.

   4) Testing of specific fixed-infrastructure components such as local electrical circuits and circuit breakers can be considered for testing if failure could represent a significant hazard, and if testing can be performed without placing the facility at risk.

   5) Consideration may be given in some circumstances to have testing performed by an independent third party, in conjunction with the healthcare organization's clinical engineering group. The involvement of a third party may facilitate a consistent and impartial evaluation of EMI issues and proposed management strategies, and more importantly may offer an independent analysis in cases where a further level of indemnity for the healthcare facility, equipment manufacturer, and/or network service provider is desired.

   6) Ad hoc testing should be an ongoing effort and include characterization of new medical device acquisitions as well as investigation of reported EMI incidents.

   7) Assistance with obtaining test transmitter equipment and performing ad hoc testing should be requested from manufacturers and network providers.

b) It is recommended that appropriate procedures be implemented to manage EMI from mobile wireless handsets, using the results of the ad hoc testing as a guide.

   1) For mobile handsets that generally transmit at a constant output power, having no dynamic power control (standard radios, family radios, two-way pagers, 802.11b / local area network systems), management should involve ensuring adequate separation from susceptible medical devices, and if possible be based on the results of on-site ad hoc testing. In the case of standard radios with relatively high power output (~2-5 watts), this may require significant separation distances and possibly necessitate their restriction from areas of the healthcare facility where sensitive medical devices are used. In the case of pagers with extremely short burst transmissions or 802.11 a/b/g / LAN or 802.15 / Bluetooth / zigbee / 802.15.3a PAN equipment with relatively low power output (~10 milliwatts), testing may reveal that separation distance recommendations are limited to only a few (if any) medical devices and require minimal or no separation.

2) If mobile wireless transmitters are dynamically power controlled (mobile phones, PDAs operating on wide area networks), then network characterization, design, and engineering should be employed as necessary to ensure that the handsets are directed to transmit at power levels below the threshold for EMI, especially in areas where many medical devices are used. The existence of numerous shielding and reflecting objects in a healthcare facility may create areas with variations in downlink signal coverage, some of which could lead to significant intermittent changes in transmit power of the handsets causing them to deviate from their normal output power. Such areas should be characterized (by measuring existing signal strength with the mobile wireless handset set to a "trace" mode — this can often be done by the network service provider) and managed appropriately.

3) Medical device management procedures may include identification through labelling, repositioning, shielding and/or filtering, or replacing particularly susceptible devices.

Note Permanent modifications to a medical device should only be made by the device manufacturer.

4) User guidelines can be provided as an additional layer of management to direct healthcare organization staff to maintain a predetermined separation distance that is both sufficient and practical (between 25 cm and 2 m) between their mobile wireless handsets and sensitive medical devices.

5) The AAMI TIR 18 is recommended for additional details on medical device management and EMC/EMI guidelines.

6) Assistance with testing and system design and engineering should be requested from the equipment manufacturers and network providers of peer-to-peer, LAN, or WAN / mobile phone systems.

c) RF emissions from in-building system network antennas (WAN microcells or repeaters, LAN access points) are most appropriately managed by locating them in a place where separation distance mitigates medical device EMI effects, such as the roof of corridors and rooms.

d) RF emissions from base station sites physically located on healthcare facility roof-top or building structures should conform to existing national radio regulations to limit emissions directly into the supporting building structure.

4.6 Non-controlled use within healthcare facilities

For non-controlled mobile wireless equipment that may be brought randomly into the healthcare facility by visitors, patients, or staff and transmit a variety of different signals at different output power and/or under different power control:

a) Separate EMC/EMI management policies than those listed for controlled mobile wireless handsets should be applied. While ad hoc testing and management solutions are always encouraged whenever possible, this may not be practical or feasible for every wireless system.

1) While certain mobile handsets may be able to operate compatibly throughout a healthcare facility environment, other mobile handsets may have greater potential to cause EMI events due to differences in output power or signal type. As the number of handsets continues to increase and new models reduce size, internalize antennas, and combine technologies (i.e. mobile phone / pager / PDA device / local area 802.11a/b/g / personal area 802.15.1 / 802.15.3a / 802.15.4, etc.), it is becoming increasingly difficult to differentiate between RF transmitter types based upon visual appearance alone. Further confounders include the growing number of wireless headsets and accessories that relocate the actual RF transmitter to a pocket or purse keeping them from obvious view even when in use. An increasing number of mobile wireless handsets can transmit multiple signal types, including data transmission that may use different bursting technologies (i.e. GPRS, WAP). Wireless laptop cards and PDAs may operate on either wide area (mobile phone-type) or local (802.11.x - type) networks with different carrier frequencies, signal types, and power output. Ultimately, it may be impossible to enforce any policy that differentiates between different non-controlled mobile wireless handset types with regard to their use in the healthcare facility based upon visual appearance. For this reason, all non-controlled mobile wireless handsets should be

treated with the same management / restrictions regardless of whether or not they appear to be the same as controlled handsets.

2) Restrictive policies might involve requesting that individuals not use their personal mobile wireless handsets in areas of the facility where sensitive medical devices are in operation. This should involve requesting by appropriately positioned signs or some other reliable mechanism that non-controlled mobile wireless equipment be turned off before entering sensitive areas, as even well-intentioned individuals may feel compelled to receive and respond to incoming calls or messages.

3) Implementation and enforcement of restrictive policies should be facilitated by defining numerous areas throughout the healthcare facility that can be easily accessed and where the use of wireless handsets by patients, visitors, and staff is permitted and encouraged.

4) Any restrictive policy should be balanced between an informed assessment of EMI risk and the increasing need among patients, visitors, and healthcare facility staff for mobile wireless communication and computing. In the extreme, healthcare facilities could ban the use of all non-controlled mobile wireless handsets altogether, although such measures may be excessive from an EMI management perspective and not responsive to the growing needs of individuals for direct access to mobile wireless communication, especially in times of emergency and crisis.

b) EMI management should be ongoing, verifying and characterizing any reported incident and making any necessary adjustments to policy.

c) Signs should be placed throughout the healthcare facility, especially in areas where sensitive medical devices are commonly located, to make patients and visitors aware of the existing healthcare facility policy.

d) While instructing patients and visitors to maintain a minimum separation distance between their personal mobile wireless handsets and medical devices might theoretically act as a safeguard against EMI events, such a recommendation may be impractical in many facility areas, and further be exceedingly difficult to monitor and enforce. Such minimum separation requirements are not recommended as a primary management strategy. However, the minimum separation distances determined from ad hoc testing should be used to identify sensitive areas of the healthcare facility.

4.7 Medical devices within healthcare facilities

Medical devices found in ad hoc testing to be susceptible to EMI should be replaced (as feasible and practical) with more immune devices, e.g. those compliant with new IEC 60601-1-2 and other relevant immunity requirements. (Medical devices that meet 60601-1-2 can still be susceptible to mobile phones at close range.)

For medical devices used outside the healthcare facility in a domiciliary setting, such as dialysis equipment, blood glucose analyser, infusion pumps, etc., instruction should be provided to patients advising them to maintain at least 1 m of separation distance between the medical device and mobile wireless equipment while it is in operation.

Although outside the current scope of this recommendation, the placement and operation of RF-emitting medical devices within the healthcare environment is an area that should be carefully considered. Electric scalpels often generate microwaves for cauterization purposes, physio-diathermy units may emit 915, 433, 2450 MHz or other frequencies for deep tissue heating (36), and ultrasound machines may radiate up to their operating frequency of ~3 to 20 MHz.

RFID tags used in the healthcare environment are passive emitters, activated by inductive processes when brought into proximity of RFID readers. However, the readers emit high field strength magnetic fields and should be included as a transmitter in ad hoc testing and in EMC/EMI management policies.

Annex A
(informative)

RF technologies

A.1 Propagation of RF energy through space

Radio frequency waves (300 kHz to 300 GHz) travel through space at the speed of light with wavelength related to the frequency and (in a vacuum) by the following equation:

Frequency (MHz) × wavelength (metres) = speed of light = 3 × 108 m/s

Table A.1 — RF propagation characteristics

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

Frequency (MHz)	Wavelength (m)
100	3
300	1
1000	0,3
3000	0,1

Because RF electromagnetic energy propagates through space, it can affect medical devices that are located remotely to the source of RF energy. Interference can be more likely to occur at RF frequencies at which the cables, wires, printed circuit board traces, and components of medical device are odd multiples of one-fourth of the wavelength. However, in intense RF fields and/or for susceptible circuitry, effects may be observed for longer and/or shorter conductors, including those as small as approximately 1/20 of the wavelength.

A.2 Electric and magnetic fields

RF energy is comprised of two interrelated components, electric (E) and magnetic (H) fields. It is usually expressed in terms of the magnitude of the electric field vector, in volts per metre, but may also be measured in terms of the magnitude of the magnetic field vector, in amperes per metre. For measurements in the near field, where the distance from the source is small compared to the wavelength, the term *electric field strength* or *magnetic field strength* is used according to whether the resultant E field or H field is measured. At lower frequencies (below 100 MHz), measurements are typically made in the near field. The E and H field strengths fall off with respect to the distance from the source. However, very close to a source, such as a cellular telephone, the field strengths can be quite high.

Unintended coupling of E fields to medical devices can occurs through relatively straight cables, wires and printed circuit board traces, and can occur at large distances from the RF source. Unintended coupling of H fields to medical devices can occur through coiled cables, wire loops, and loops formed by printed circuit board traces, usually very close to the RF source.

A.3 Minimal separation distances

In the far field (distance greater than the sum of several wavelengths of the transmitter carrier frequency), and for typical antennas, the field strength from a transmitter varies proportionally to the inverse of the distance from the transmitter. If the output power of a transmitter is known, the dipole equation can be used to calculate an estimate of the field strength in the far field as a function of distance. If the radiated RF immunity of a

medical device is known, an estimation of immunity can be made by substituting immunity for the field strength and solving the dipole equation for distance:

$$d = [k \sqrt{\ } P] / E$$

where

P is the output power of the transmitter in watts;

E is the immunity of the medical device in volts per metre;

d is the minimum separation distance in metres;

k is a constant in the range of 0,45 to 7, depending on the antenna efficiency of the transmitter.

The value of k for cellular telephones is approximately 7, and the value for lower-frequency hand-held transmitters such as walkie-talkies can be as low as 3.

This approximation does not apply at distances less than several wavelengths of the transmitter carrier frequency (i.e. in the near field). The limitations of this estimate are described below. The following is assumed:

— a single transmitter is present, radiating at its maximum rated power; and

— the worst-case susceptibility of the medical device occurs at the frequency of the transmitter.

In addition, if multiple RF transmitters (e.g. mobile telephones) are in use, the minimum separation distance necessary for compatible operation could be greater than that determined from this equation. If a single RF transmitter is radiating less than its maximum power rating or the worst-case susceptibility of the medical device occurs at a frequency other than that of the RF transmitter of interest, the actual minimum separation distance could be less than that determined from the equation. The actual minimum separation distance is also affected by antenna efficiency, radiation pattern, and by absorbing and reflecting objects (including buildings and people). Multipath reflections could result in a minimum separation distance greater than that determined from the equation, and absorption could result in a minimum separation distance less than that determined from the equation.

A.4 Mobile phone technologies

A.4.1 General network considerations

Mobile phones operate on WANs composed of numerous cell sites using different RF signal technologies. Common first generation (1G) analogue technology includes AMPS systems in the US, NMT [Nordic Mobile Telephony] technology in Scandinavia as well as parts of Russia / Eastern Europe / Mid East / Asia, and TACS in Europe and other parts of the world. These systems as well as smaller systems in France, Germany, Italy, Canada, and elsewhere are now largely obsolete or being phased out in many parts of the world where newer digital technologies are predominant.

Analogue technology assigns a single channel frequency per user, while newer second generation (2G) “digital” technologies allow multiple users to operate on a single channel frequency creating more capacity on the network by converting voice data into a binary form (0's and 1's) and compressing it.

Second generation technologies in the US include CDMA and a variety of different TDMA-type technologies including NADC (which is rapidly being phased out), GSM and iDEN. In Europe, parts of Asia, and other locations, the predominant technology is GSM, with Tetra (Terrestrial Trunked Radio) also used in many parts of Europe by public safety departments.

With CDMA, the compressed data are sent in small pieces at discrete frequencies over a series of 40 contiguous channels, or ~1,2 MHz of frequency spectrum, with multiple calls overlaid on top of each other. Each call is then deciphered from the noise floor (composed of all the other callers using that channel block at that time) by its unique sequence code.

With TDMA, transmission occurs at a single channel frequency, but each user is assigned a specific "time slot" that occurs within a repeating time element (a "frame") in which to pulse their compressed voice data. The different TDMA technologies have different protocols that define the "pulse" parameters. Other mobile phone technologies that are specific for areas in Asia include Japan CDMA, JTACS [Japanese Total Access Communications System], Japan PDC [Personal Digital Cellular], and Korean PCS [Personal Communications Services].

A global standard for third generation (3G) wireless communications has been defined by the International Telecommunication Union (ITU) and will implement CDMA technologies engineered to allow more room for data transmissions (up 1-to 2 Mbps as opposed to the 10's of Kbps of 2G technologies) for Internet surfing, downloading video, etc.

The common form in Europe called UMTS [Universal Mobile Telecommunications Systems] and is a wide band CMDA (WCDMA) technology having a bandwidth of ~5 MHz (as opposed to the 1,2 MHz of conventional CDMA) and is starting to take hold in some of the larger metropolitan European regions. In Japan, a similar WCDMA technology is called FOMA [Freedom of Mobile Multimedia Access].

A competing technology in the US is CDMA-2000, which utilizes the conventional 1,2 MHz bandwidth but allows for a much higher data rate and can operate not only on the existing frequency bands but also on the newly allocated 3G bands as well.

As technology continues to develop, mobile phones allowing simultaneous voice and data communication using GPRS, WAPs, and other technologies are becoming increasingly common. Such data transmissions generally emit RF signals as bursts during periods of system availability using the embedded signal technology and under normal power control of the phone on a dedicated data channel.

A.4.2 Mobile phone emissions — Frequency

The FCC in the United States has allocated specific blocks of frequency spectrum that mobile phone handsets and network base stations use to transmit on during operation. Various network companies license the rights for use of all or parts of these blocks of spectrum in various geographical areas.

Initially during power-up (or hand-off), a process of registration occurs on a random access or unassigned control channel frequency that facilitates bidirectional communication between the phone and the base station to exchange registration information.

Following that process, the phone is assigned a dedicated channel frequency to receive call information (called a "downlink channel" or "Rx") and in return is directed to transmit on an assigned "traffic" channel that is commonly 25 to 50 MHz lower in frequency (called the "uplink channel" or "Tx").

As the user crosses over to another location area (i.e. a cluster of cell sites linked within the network covering a particular vicinity), he/she will be "handed-off" and assigned new non-overlapping Tx / Rx channels (following another re-registration process) by the next base station.

The original frequency block in the United States (824-849 MHz Tx / 869-894 MHz Rx) still supports analogue, CDMA, and NADC-TDMA technologies, although NADC is rapidly being phased out and in its place GSM technology is being implemented. Each channel within this block is 30 kHz wide, and Rx = Tx – 45 MHz. As room within this frequency block became insufficient for the growing number of mobile phone users, another larger block of spectrum was opened up by the FCC for newer second generation CDMA and TDMA technologies at 1850-1910 MHz Tx / 1930-1990 MHz Rx with a channel width of 50 kHz and Rx = Tx – 80 MHz. iDEN technology operates in one of the many LMR frequency blocks along with public safety radio systems (806-824 MHz Tx / 851-869 Rx) and has a 25 kHz channel width, and Rx = Tx – 45 MHz.

Mobile phone emissions outside of any assigned channel frequency are minimal in the US due to compliance with FCC (Federal Communications Commission) CFR Part 15 specifications regulating the allowable level of both "spurious" and "out of band" emissions (the actual US spec is attenuation by at least 43 + 10 log10 (P) dB or 60 dB, whichever is the lesser attenuation — for a 1 watt transmitter = –13bBm or 50 microwatts. In Europe, similar specifications are defined by the International Telecommunications Union (ITU) Radiocommunication Assembly ITU-R SM.329, which sets spurious emissions limits at -16 dBm or 25 microwatts for a 1-watt transmitter in the 900 MHz band (< 960 MHz) and 100 microwatts for a 1-watt transmitter with a carrier frequency of 960 MHz–17,7 GHz).

A.4.3 Mobile phone emissions — Output power

When in use, mobile phones transmit on their assigned Tx channel at an output power that is continuously regulated (many times per second) over a range of incremental power steps as it moves through the network in a manner more or less inversely proportional to the base station (Rx) signal strength.

This situation is actually a bit more complex due to the ability of some systems to set different thresholds to initiate power cutback, switch operation to other networks when they cross coverage boundaries and exceed traffic volumes, etc., but the basic description serves for the purpose of this commentary.

Normally, the maximal transmit power of a mobile phone ranges from ~0,6 to 2 watts (depending upon the technology). At the lowest transmit power, the phone may emit a few milliwatts or less. By comparison, 802,11b local area network devices typically transmit continuously at ~10 milliwatts.

Because TDMA signals are emitted in a pulsed fashion, their average power is lower than their pulsed power (for example, with GSM technology there are eight possible time slots per channel so an output power of 1 watt emitted repeatedly during a single time slot, followed by seven time slots where no power is emitted, would translate into an average power of 1 W / 8 = 125 milliwatts). For analogue and CDMA signals, power is emitted in a more continuous fashion, albeit for CDMA the power is spread over ~1,2 MHz.

As an individual mobile phone moves through the network, or even within a building, the output power may fluctuate significantly due to numerous reflecting and shielding structures that influence the path of the RF signal. The handset is constantly directed to transmit at the lowest power control level necessary to maintain a sufficient link, because the lower the Tx power, the longer the battery life and the less possibility of interference with other mobile phones. Sporadic "shadow" coverage areas that cause phone handsets to transmit at significantly higher power levels may be especially problematic in hospital buildings with complex floor plans, lead-impregnated walls in radiology / oncology units, and basement levels.

When analogue and TDMA mobile phones cross over to another location area, the hand-off is "hard", meaning that each new registration is performed at full power and then subsequently power controlled by the new base station after 1 to 2 seconds. For CDMA technologies, the hand-off is "soft", meaning that power control is maintained during the hand-off and continually regulated so as not to overwhelm the more tightly power-controlled nature of the CDMA system.

A scenario where mobile phones on some (but not all) technologies can change power can occur when traffic on the local base station within the network has reached capacity and users are transferred to distal sites, coming under the direction (and power control) of the more distant base station. Other technologies simply register a "system busy" message and drop from the network. While both situations can be problematic, both can be avoided if adequate room is available on the network for the local communication traffic.

One final aspect of newer digital mobile phone technology that can influence output power in TDMA-type technologies is delayed transmission (DTx), or the ability of the network to direct a mobile phone handset to further compress its voice data during times of speech inactivity and only send it out during periodic pulses. A similar function in CDMA networks is variable rate speech coding that can assign a lowered data rate level during speech inactivity. The result of each is a markedly reduced transmission (just enough to hear a background "hiss" so the speaker knows he is still connected to someone) with the phone actually not transmitting over a majority of the time during speech inactivity.