Draft Guidance for Industry and FDA Staff

Radio-Frequency Wireless Technology in Medical Devices

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Draft released for comment on [*OSM will insert release date of FR Notice on posting*]

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Alternatively, electronic comments may be submitted to http://www.fda.gov/dockets/ecomments. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact Donald M. Witters Jr. at 301-827-4955, or by e-mail at Donald.Witters@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Electrophysics Branch
Division of Physical Science
Office of Science and Engineering Laboratories

2006D-0504

GDL 1

Preface

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/[specific address]. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number (1618) to identify the guidance you are requesting.

Table of Contents

1. Introduction 3
2. Scope 4
3. Definitions 5
4. Concerns Related to RF Wireless Technology Use in and Around Medical Devices 6
5. Risk Management for RF Wireless Medical Devices: General Concepts 11
6. Design and Development 12
7. Design and Development Verification 15
8. Design and Development Validation 18
9. Labeling 19
10. Purchasing Controls and Acceptance Activities 21
11. Corrective and Preventive Action 21
12. Servicing 22
Appendix A: Additional Information About RF Wireless Communications 24
Appendix B: Reference Standards and Telecommunications Information 26

Draft Guidance for Industry and FDA Staff

Radio Frequency Wireless Technology in Medical Devices

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Introduction

FDA has developed this draft guidance document to assist industry, systems and service providers, consultants, FDA staff, and others in the design, development, and evaluation of radio frequency (RF) wireless technology in medical devices. This guidance references national and international standards and discusses some of FDA's regulatory requirements for medical devices including premarket and postmarket requirements under the Quality System regulation (QS regulation) (21 CFR part 820).[1]

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least

[1] The QS regulation is applicable to any finished device (21 CFR 820.1). The regulation for design controls, 21 CFR 820.30, applies to class III, class II, and specific class I devices, including devices automated with computer software.

burdensome way for you to comply with those requirements. However, if you believe an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/ombudsman/.

2. Scope

This draft guidance document addresses issues and concerns pertinent to the safe and effective use of radio frequency (RF) wireless technology in medical devices, including:

- wireless coexistence
- performance
- data integrity
- security
- electromagnetic compatibility (EMC).

Since these issues affect all stages of the product life cycle, FDA recommends they be considered in:

- identification, documentation, and implementation of product design requirements (21 CFR 820.30)
- design verification and validation (21 CFR 820.30)
- risk management processes and procedures.

As required by QS Regulation, 21 CFR 820.30, you must establish and maintain procedures to control the design and development of devices to ensure that specified design requirements (21 U.S.C. 301 et seq.) are met. This document discusses the following considerations specific to RF wireless technology in medical devices that should be considered in addition to general medical device requirements:

- design and development activities
- risk management activities
- testing
- labeling
- purchasing controls
- acceptance activities
- servicing

- corrective and preventive action (CAPA) considerations.

Current RF wireless technologies include: 47 CFR Part 15 (Federal Communications Commission (FCC Part 15) devices[2], Wireless Medical Telemetry Service (WMTS), cellular (mobile) telephones, wireless computers and personal digital assistants (PDAs), and RF identification (RFID).

3. Definitions

Electromagnetic compatibility (EMC) — the ability of a device to function (a) properly in its intended electromagnetic environment, and (b) without introducing excessive electromagnetic energy that may interfere with other devices

Electromagnetic disturbance (EMD) — any electromagnetic phenomenon that may degrade the performance of equipment, such as medical devices or any electronic equipment. Examples include power line voltage dips and interruptions, electrical fast transients (EFTs), electromagnetic fields **(radiated emissions), electrostatic discharges**, and **conducted emissions**

Electromagnetic interference (EMI) — degradation of the performance of a piece of equipment, transmission channel, or system (such as medical devices) caused by an electromagnetic disturbance

Electrostatic discharge (ESD) — the rapid transfer of electrostatic charge between bodies of different electrostatic potential, either in proximity in air (air discharge) or through direct contact (contact discharge)

Emissions — electromagnetic energy emanating from a device generally falling into two categories: conducted and radiated. Both categories of emission may occur simultaneously, depending on the configuration of the device

> **Conducted emissions** — electromagnetic energy emanating from a product through a conductor by means of resistance, inductance, or capacitance. Conductors include AC power cords, metallic enclosures of a subsystem, or cables interconnecting subsystems or the patient to the product. Conducted emissions include power line harmonics, surges, and radio frequency energy, especially in the frequency range 150 kHz to 80 MHz
>
> **Radiated emissions** — electromagnetic energy emanating from a device and propagating through space or a medium (which can affect the distance and direction of propagation). **Radiated emissions** include both intentional emissions such as radio transmissions carrying information and unintentional emissions associated with electrically powered equipment such as motors, power supplies, and computer components

[2] 47 CFR 15.3.

Immunity — the ability of an electrical or electronic product to operate as intended without performance degradation in the presence of an **electromagnetic disturbance**

Latency — the time it takes for a unit of information to cross a wireless link or network connection, from sender to receiver

Quality of service (QoS) — an agreed-upon level of performance in a data communications system or other service, typically encompassing multiple performance parameters, such as reliability of data transmission, transfer rate, error rate, and mechanisms and priority levels for time-critical signals

Radio frequency (RF) — a frequency in the portion of the electromagnetic spectrum that is between the audio and the infrared portions; commonly used radio frequencies range from 9 kHz to 100 GHz

Radio-frequency interference (RFI) — one type of **EMI**, resulting from **radiated emissions** at one or more radio frequencies

Radio-frequency (RF) wireless medical device — a medical device that includes at least one function that is implemented using RF wireless communications; examples of functions that may be implemented wirelessly include data transfer, device control, programming, power transmission, remote sensing and monitoring, and identification

Susceptibility — the potential for equipment (such as medical devices) to respond to an **electromagnetic disturbance**

Vulnerability — see **susceptibility**

Wireless coexistence — the ability of one wireless system to perform a task in a given shared environment where other systems (in that environment) have an ability to perform their tasks and may or may not be using the same set of rules.[3]

4. Concerns Related to RF Wireless Technology Use in and Around Medical Devices

In general, a wired connection is more reliable than a wireless connection. FDA believes the more critical the medical device function and information passed via RF technology, the more important it is the wireless connection be robust. We recognize there are several concerns about the potential effects of RF wireless technology in and around

---

[3] For more information, see standards such as IEEE 802.15.2 Coexistence of Wireless Personal Area Networks with Other Wireless Devices Operating in Unlicensed Frequency Bands.

medical devices related to the ability of the devices to function properly and the resultant safety of patients and operators, including:

- RF wireless emissions from one product or device can affect the function of another
- electromagnetic environments where medical devices are used may contain many sources of RF energy
- the use of RF wireless technology in and around medical devices is increasing.

To further protect against electromagnetic interference (EMI) to other medical devices in the vicinity, FDA recommends wireless medical devices limit their RF output to the lowest power necessary to reliably accomplish their intended functions.

FDA recommends you address the following issues regarding expected characteristics of the electromagnetic environment where your device will be used:

- performance of wireless functions
- wireless coexistence
- wireless quality of service
- integrity of data transmitted wirelessly
- security of data transmitted wirelessly and wireless network access
- EMC.

The following discusses these issues in more detail.

Performance of wireless functions

Correct and timely transmission of medical data and information is essential for the safety and effectiveness of both wired and wireless medical devices and systems. However, medical electrical equipment following with the IEC 60601-1-2:2001 "Medical Electrical Equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests" is presently exempt from the electromagnetic immunity provisions in the "exclusion band" (passband) of RF frequencies where the medical device RF wireless receiver or transmitter operates. This means that IEC 60601-1-2:2001 is presently inadequate to assess if the wireless link will operate properly in the presence of in-band EMD. Thus, FDA recommends you describe in your premarket submission and labeling the wireless technology and RF specifications (e.g., RF frequency and modulation), the testing performed, and your results demonstrating the wireless functions will operate safely and effectively in the intended use environment.

Wireless coexistence

A key factor contributing to a wireless medical device's safety and effectiveness is the limited amount of RF spectrum available and potential competition among wireless technologies for the same spectrum. This is managed in different ways for different RF wireless communication technologies that may be available for use in healthcare communication and health informatics exchange. FDA recommends you address the selection of appropriate RF wireless communication technologies in your design and development process, including it as part of the risk management process.

Current RF wireless technologies include:

- 47 CFR Part 15 (Federal Communications Commission (FCC Part 15) devices
- Wireless Medical Telemetry Service (WMTS)
- cellular (mobile) telephones
- wireless handheld computers and personnel digital assistants (PDAs)
- wireless local area networks (WLAN 802.11.a/b/g)
- wireless modems for laptop computers
- personal area networks including 802.15.1 (Bluetooth), 802.153a (ultrawide band) (UWB), and 802.15.4 (Zigbee)
- RF identification (RFID).

Each type of wireless technology faces coexistence challenges. For example, devices operating under FCC Part 15 rules are subject to interference from primary users of the frequency band. There can be a problem when the FCC reallocates bands in which these devices operate, and bands once locally clear become occupied with primary users.

Wireless Medical Telemetry Service (WMTS) provides frequency bands in which medical telemetry devices are co-primary users. Frequency coordination is performed by the American Hospital Association (AHA). However, in some locations, sidebands from powerful TV transmitters in adjacent bands may make portions of the allocated WMTS spectrum unusable. In some locations, military radars still have primary authorization to use portions of the WMTS bands.

Wireless quality of service

While the quality of service of cellular networks may be acceptable for voice communication, it may not be sufficient for medical functions. Connections lost without warning, failure to establish connections, or even slight degradation of service can have serious consequences, especially for:

- wireless transmission of critical medical device alarms

- continuous physiological waveform data
- real-time control of therapeutic medical devices (such as wireless footswitches)
- time-critical medical telemetry (such as for real-time patient waveforms and alarms)
- wireless control of therapeutic devices.

Integrity of data transmitted wirelessly
Many RF wireless devices use the industrial, scientific, and medical (ISM) frequency bands such as 2.4GHz, and these can incorporate technology to minimize interference and data errors or corruption (e.g., RF frequency hopping protocols). However, wireless coexistence and data latency remain concerns because the data transfer rate can slow slightly or even dramatically with an increase in the number of similar transmitters in a given location. In many cases it is essential that medical data, including real-time waveforms and critical control signals and alarms, be transmitted and received without error.

Security of data transmitted wirelessly and wireless network access
Security is a concern in the use of RF wireless technology because it can be easier for unauthorized eavesdropping on patient data or unauthorized access to hospital networks to occur.

EMC
FDA recommends electromagnetic compatibility (EMC) be an integral part of your design, testing, and performance for RF wireless medical devices. Voluntary consensus standards such as the IEC 60601-1-2:2001 "Medical Electrical Equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests" (IEC 60601-1-2:2001) provide electromagnetic emissions and immunity requirements for medical electrical equipment. However, as noted above, RF receivers are exempt in this standard from immunity provisions in their passband.

Therefore, FDA recommends you indicate in your premarket submission and as part of your QS records:

- whether you used the exclusion band allowance
- testing you performed to demonstrate the wireless function will operate as intended in the expected environment of use.

Brief summary of examples of potentially problematic situations
Use of RF technology could have the following results:

- signal from wireless footswitch or microphone is delayed or blocked, and therapy is not terminated when intended
- EMI causes erroneous wireless programming of a medical device
- unauthorized person gains access to a healthcare facility network and causes damage in other networked equipment or denial of service of the network
- unauthorized person gains access to private medical information
- too many nearby in-band RF transmitters (such as frequency hopping spread spectrum) increase latency, slow down, or block transmission of continuous, critical patient data, and life-threatening conditions are not communicated to caregivers in a timely manner
- cellular telephone network is used for transmission of continuous, critical patient data, and connection is dropped, resulting in loss of data or critical alarms missed
- cellular telephone network is used to communicate critical alarms directly to caregivers, but calls do not go through
- RF wireless transmissions cause EMI in other nearby medical devices.

Examples of problems reported with RF wireless medical devices

A doctor used an incorrect wireless microphone with an endoscopic positioning system, causing the positioner to move without command during surgery.[4]

A wireless deep brain stimulator was incorrectly reprogrammed during a status check.[5]

The following is a report of the vulnerability of RF wireless networks: Denial of Service Vulnerability in IEEE 802.11 Wireless Devices.[6]

---

[4] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=527093.

[5] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=465394.

[6] Denial of Service Vulnerability in IEEE 802.11 Wireless Devices, http://www.auscert.org.au/4091.

5. Risk Management for RF Wireless Medical Devices: General Concepts

FDA recommends you manage risks associated with RF wireless technology as part of a comprehensive quality management system. ISO 14971:2000 Medical Devices - Risk Management - Part 1: Application of Risk Analysis can be a useful tool to help satisfy some of the design control requirements specified by 21 CFR 820.30. Refer to **Section 4. Concerns Related to RF Wireless Technology Use In and Around Medical Devices (above)** for a detailed discussion on issues that you should address in the risk analysis.

When establishing the scope of your risk management effort, FDA recommends you consider:

- intended use
- foreseeable misuse
- sources of environmental EMD (e.g., radio transmitters, computer RF wireless equipment)
- potential to affect other devices.

For this process, FDA recommends you manage the risks systematically using risk analysis, risk evaluation, and risk controls. We recommend you prioritize risks according to severity of consequences and probability of harm. For example, we recommend you use reports of EMI-related events and other relevant experience when estimating probability of occurrence.

FDA recommends you address known safety issues involving RF wireless technologies early in the design and development process. For example, where multiple alarms are incorporated into a device or system via wireless links, we recommend you address:

- specific requirements needed to ensure each alarm is distinct and discernable from others (see 21 CFR 820.20)
- priorities for accessing the wireless system
- priorities related to the function of the wireless technology itself.

You may identify other safety issues as the design and development proceeds, and risk control measures may be necessary to ensure an overall acceptable level of risk. FDA recommends risk acceptability criteria be based on information about the device and its use including, but not limited to:

- applicable standards
- accepted design practices

- experience with similar devices.

6. Design and Development

Based on intended use and anticipated environments for your medical device, FDA recommends you address the following factors in the device design and development:

- intended use related to the RF wireless functions, including any use limitations
- device performance and specifications related to RF wireless functions
- wireless coexistence
- wireless quality of service
- integrity of data transmitted wirelessly, including latency and throughput
- security of data transmitted wirelessly, including protection against unauthorized wireless access to device control or data (e.g., encryption, data access controls).
- wireless network access
- limitations or restrictions for proper operation and RF wireless communications
- how users will interact with the system
- software
- applicable EMC and telecommunications standards and regulations, including device RF emissions that may cause EMI with other equipment
- environmental requirements
- risk analysis and control measures

Device performance and physical specifications

We recommend you address:

- all functions and features implemented with RF wireless
- detailed performance specifications
- safety-related requirements of your device
- transmitter/receiver parameters including the operating frequency and RF output power
- wireless protocol specification name or designation (e.g., WMTS, IEEE 802.11b)

- restrictions on the number or characteristics of other in-band transmitters
- performance when RF wireless link is lost or corrupted (e.g., alarms, back-up functions, alternative modes of operation)

Software

For RF wireless devices that use computer programs (software), we recommend you describe the program's ability to handle device responses and failures under EMI conditions. FDA suggests you consider, as a risk control measure, software designed to handle failures of RF wireless technologies. When there is a change to the software, we recommend you provide an evaluation to ensure risk acceptability criteria are maintained.

EMC and Telecommunications

FDA also recommends you describe, in your premarket submission and as part of your QS records, EMC-related device shielding and filtering to protect against EMI from:

- other medical devices
- consumer products
- commercial and private radio transmissions
- power line disturbances
- other sources of EMD.

We recommend you design and test RF wireless medical devices for EMC performance using appropriate standards (e.g., IEC 60601-1-2:2001, recognized by FDA). See also AAMI Technical Information Report 18 (AAMI TIR No. 18-1997, Guidance on Electromagnetic Compatibility of Medical Devices for Clinical/Biomedical Engineers—Part 1: Radiated Radio-Frequency Electromagnetic Energy).

Environmental requirements

FDA recommends you address your device's environmental requirements, including:

- device temperature and humidity limitations
- associated sources of EMD expected in specific use environments.

The following examples illustrate RF sources in medical device use areas.

Surgical rooms

- wireless operating room controllers

- wireless monitors
- cellular (mobile) phones
- wireless PDAs (depending on restrictions)
- RFID
- high-frequency surgical devices
- diathermy
- other RF-emitting devices.

Intensive care units

- WLAN
- wireless monitors
- cellular (mobile) phones
- wireless PDAs
- RFID
- other RF emitting devices.

Intermediate care or step-down unit

- cellular (mobile) phones
- wireless PDAs
- RFID
- other RF emitting devices

Emergency vehicles

- high RF power vehicle and portable transmitter radios
- radars
- RF toll systems (e.g., EZ Pass)

Ambulatory and transport

- cellular (mobile) phones
- two-way radios
- metal detectors
- security systems
- RFID
- RF toll systems (e.g., EZ Pass)

Home

- cellular (mobile) phones
- wireless PDAs
- appliances
- electronic products
- two-way radios
- amateur radio

Risk analysis and control measures

As part of your design validation,[7] FDA recommends you perform a risk analysis, as early as possible, to determine how your device could cause harm and how it will perform as part of the design validation. (See the Quality System regulation (21 CFR Part 820) and preamble.[8])

We recommend you identify:

- possible adverse outcomes
- severity of harm
- possible causes of adverse outcomes (including those originating with RF wireless systems)
- risk control measures to reduce risks.

FDA recommends you continually update the risk analysis throughout the design and development process as more information becomes available.

We recommend you use the results of the risk analysis to establish and refine the design specifications. Because RF wireless systems are inherently less reliable than hardwired ones, we recommend you identify which device functions should be made wireless and which should not.

7. Design and Development Verification

To determine if your device performs according to design and development input specifications,[9] FDA recommends you conduct verification testing of:

---

[7] Design validation shall include ... risk analysis, where appropriate. 21 CFR 820.30(g). A requirement qualified by "where appropriate" is deemed by FDA to be "appropriate" unless the manufacturer can document justification otherwise. 21 CFR 820.1(a)(3).

[8] 61 FR 52602 at 52621, Comment 83 (October 7, 1996).

[9] Design verification is discussed at 21 CFR 820.30(f).

- RF wireless medical device communication
- control functions
- EMC.

For RF wireless communications and control functions, FDA recommends you test your device to verify conformance to applicable telecommunications standards and regulations, and to determine if the device's functions are not compromised under expected environmental conditions for use.

For EMC, FDA recommends you test both electromagnetic emissions and immunity. We recommend device EMC immunity test levels be representative of the intended electromagnetic environment of use. We recommend your testing include:

- electrostatic discharge (ESD)
- radiated RF electromagnetic energy
- conducted RF electromagnetic energy
- magnetic fields.

For AC-powered devices, we recommend your testing include:

- electrical fast transients and bursts
- surges
- voltage dips
- short interruptions
- voltage variations on power supply input lines.

Testing of the function of RF wireless subsystems in the presence of EMD in their passband is not necessary under IEC 60601-1-2:2001, but there are reference standards that may be applicable (e.g., ETSI EN 302 195-1, Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 9 kHz to 315 kHz for Ultra Low Power Active Medical Implants and Accessories; Part 1: Technical characteristics and test methods).

FDA recommends you verify your RF wireless technology will function properly in its expected use environment, addressing:

- RF frequency and modulation
- data transmission rate
- quality of service

- bit error rate
- latency
- wireless communications reliability in relation to the primary medical device functions and operation with other in-band transmitters
- device and wireless communications safety features
- data security features.

FDA also recommends the wireless technology itself (and in conjunction with the medical device) meet all applicable Federal Communication Commission (FCC) regulations and requirements (see FCC in Appendix C).

We recommend EMC be demonstrated by the device's conformance to one or both of the following standards (or their U.S. equivalent) or by equivalent methods:

- IEC 60601-1-2:2001 Medical Electrical Equipment - Part 1: General Requirements for Safety; Electromagnetic Compatibility - Requirements and Tests
- IEC 61326 Electrical equipment for measurement, control and laboratory use – EMC requirements.

FDA recommends the device design and development verification process include:

- expected use environments
- all claims for device use and RF wireless functions
- summary of all limitations, warnings, and contraindications regarding RF wireless technology and EMC
- brief summary of all RF wireless and EMC testing and findings
- brief explanation of any device EMC or other modifications needed to pass any testing.

We recommend the RF wireless and EMC testing and results be summarized in your premarket submission and labeling, in a table containing the following information:

- tests performed (e.g., RF wireless performance, EMC immunity and emissions)
- References to appropriate medical device, RF wireless technology, or EMC standards for the tests
- explanations for any deviations from the selected standards

- mode(s) of device operation during testing, with an explanation of significance of these modes
- test levels or limits
- specific device-related acceptability criteria for each device mode or function test
- specific device functions that may not degrade (such as CPU failure)
- device functions that may degrade (such as display fluctuation)
- rationale for how each device function was categorized
- description of and justification for modifications to device to pass any EMC test
- if modifications were made, a statement that all modifications will be incorporated into all production units.

FDA recommends verification of the risk acceptability of wireless system risks also be performed or incorporated into testing. For example, a verification for a risk might be confirmation that a performance provision is met or a risk control method is effective.

8. Design and Development Validation

FDA recommends you validate your device under actual or simulated use conditions to ensure the device conforms to defined user needs and intended uses.[10] Design validation may include RF wireless communications and control functions if these design input functions are appropriate and address the intended use of the device, including the needs of the user and patient.[11]

FDA recommends validation also be performed under defined operating conditions on initial production units or equivalents to demonstrate results are applicable to full-scale production.[12] For example, if other in-band RF sources are expected to be used in proximity to the RF wireless medical device, we recommend you test:

- data transmission rate
- latency
- bit error rate

---

[10] 21 CFR 820.30(g).

[11] 21 CFR 820.30(c). Design requirements, for example, RF wireless communications and control functions, are "appropriate" if non-implementation could reasonably be expected to result in the product not meeting its specified requirements. 21 CFR 820.1(a)(3).

[12] 21 CFR 820.30(g).

- security of production units.

We recommend this testing be conducted in the presence of the number and type of in-band sources at the expected proximity specified for the device. FDA recommends you document the methods and results used for this validation.[13]

With the possibility of EMD affecting important functions, control measures for some risks may necessitate that an operator recognize a hazardous situation and take action to prevent harm. We recommend you perform validation of these risk controls, particularly for high-priority risks, to provide additional evidence the device is safe for use. For example, design validation may reveal that steps to reestablish an RF wireless connection needing initialization may compromise safety under some use conditions.

9. Labeling

We intend for the following suggestions to assist you in meeting the labeling requirements of 21 CFR Part 801. The premarket notification should include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). You must submit all proposed labeling in your premarket approval application (PMA). 21 CFR 814.20(b)(10). FDA recommends labeling for electrical and electronic medical devices, such as those containing RF wireless technology, include:

- equipment or system specifications
- EMC and telecommunications standards compliance or other testing performed
- EMC and telecommunications standards test results
- warnings about possible effects of RF sources (e.g., security systems, cell phones, PDAs, other in-band transmitters).

FDA recommends your labeling supplement design, testing, and risk control measures to address RF wireless issues and any precautions users should take. You should also be aware that labeling in place of design and development controls or risk controls is typically not adequate to prevent adverse events.

The FDA recognized IEC 60601-1-2;2001 standard includes extensive labeling that you should consider for applicable medical devices and systems. To help ensure safety and effectiveness of your device, FDA recommends the labeling include:

- recommended separation distances from other devices or EMD sources
- conformance to existing standards
- how testing was conducted

[13] 21 CFR 820.30(g).

- susceptibilities discovered.

Adequate labeling is particularly important if the device is often used in high field strength environments and cannot be made to function as intended in these environments. If a device cannot meet applicable test provisions, or there are competing safety issues, FDA recommends you include warnings about the potential of EMI from exposure to EMD sources and device emissions that may affect other equipment.

For medical electrical equipment and systems that include RF transmitters, FDA recommends you identify:

- each frequency or frequency band of transmission
- RF type (e.g., IEEE 802.11) and frequency characteristics of the modulation
- effective radiated power.

For medical electrical equipment and systems that include RF receivers, FDA recommends you provide:

- each frequency or frequency band of reception
- preferred frequency or frequency band, if applicable
- bandwidth of receiving section of the equipment or system in those bands
- warning that other equipment could interfere with the equipment or system, even if the other equipment complies with CISPR emission requirements.

For medical devices that include RF wireless transmitters or receivers, FDA may recommend additional labeling for:

- data throughput
- latency
- integrity
- security characteristics and associated precautions
- need for spectrum management
- limitations on number, output power, or proximity of other in-band transmitters used in vicinity.

FDA recommends you document evidence of compliance with the standard's labeling provisions. (See IEC 60601-1-2:2001). We recommend that you also refer to other FDA guidances applicable to your device for additional labeling suggestions.

10. Purchasing Controls and Acceptance Activities

In many cases, off-the-shelf RF wireless components or systems (such as those claiming conformance to IEEE 802 standards) may not have been adequately tested or qualified to address the needs and risks for use in medical devices. FDA recommends you provide procedures and controls for all device or system components, including those that may be sold as subsystems of your device, indicating the components, products, or services conform to defined design requirements (21 CFR 820.50(a)) related to the RF wireless concerns in Section 4 above.

If a contract EMC laboratory tests the wireless components or products, FDA recommends the service be treated in the same manner because these services affect the quality of the finished device. We recommend you maintain descriptions of EMC and RF wireless testing performed by a contract laboratory.[14]

FDA recommends you:

- evaluate and select suppliers on the basis of their ability to meet specified requirements (21 CFR 820.50(a))
- exercise controls over the suppliers according to evaluation results
- maintain records of acceptable suppliers.[15]

To ensure the incoming product is inspected, tested, or otherwise verified as conforming to specified requirements,[16] FDA also recommends you provide:

- written acceptance procedures
- acceptance criteria
- testing and inspection
- other acceptance and verification activities.

11. Corrective and Preventive Action

For the entire life cycle of your device, FDA recommends you consider:

- performance of RF wireless functions
- wireless coexistence
- quality of service

---

[14] 21 CFR 820.50(b).
[15] 21 CFR 820.50(a).
[16] 21 CFR 820.80(b).

- integrity of data transmitted wirelessly
- security and privacy of data transmitted wirelessly
- security and privacy of wireless network access
- EMC.

During Corrective and Preventive Action (CAPA) analysis and review, FDA recommends you look for trends in:

- nonconformance information
- complaints
- reports of failures
- service data that would identify erratic or unexpected behavior of its medical devices[17] (examples: reprogramming of deep brain stimulators, commands missed or misinterpreted by operating room controllers, unexplained inconsistencies of an infusion pump, failure to activate alarms in alarm conditions.)

To identify potential problems, FDA recommends you analyze failure trends by characteristics such as location, user application, and repeat component failures.

You may use this data to assess design specifications and if appropriate, initiate redesign or design changes.

If you identify a failure or malfunction of an RF wireless function, FDA recommends you assess any product lines that use similar designs or are subject to the same environment. We also recommend you review production and repair records to determine if data can further identify the problem as it may relate to a manufacturing step, a work station, or one or more employees.

When RF wireless or EMC problems are confirmed, you should redesign your device to prevent recurrence, which may include redesigning vulnerable circuits and possibly improving the device's RF shielding. FDA recommends labeling contain warnings or precautions to supplement the design changes.

12. Servicing

When servicing electrically powered medical devices, FDA recommends you maintain the integrity of RF wireless functions and EMC design. When servicing medical devices,

[17] 21 CFR 820.100.

we recommend care be taken to ensure EMI protection are present and in good condition. Such EMI protection can include components that may be removed during service such as shields, metal covers, ferrite beads, bonds, screws, ground wires and straps.

FDA recommends you do not paint metal surfaces that are specifically left bare for RF shielding continuity. To reduce EMI susceptibility as electronic equipment ages, we recommend you clean connector contacts that may have oxidized since oxidized contacts can act as semiconductors.

"No problem found"

FDA recommends you investigate EMI as a possible explanation for device malfunction when no problem is found in a device received for service, particularly where RF transmitters were located near the malfunctioning device. EMD from outside transmitters may be intermittent, and the electromagnetic environment of the service location can be very different from the location where a device malfunctioned. To aid in proper analysis and investigation, we recommend you identify if RF wireless transmitters or sources of EMD that were in the vicinity of the malfunctioning device.

Other common causes for "no problem found" can include:

- use error
- intermittent hardware problems
- software "bugs."

Appendix A: Additional Information About RF Wireless Communications

The following mobile wireless equipment can transmit on exclusive licensed frequencies:

- most mobile phones
- pagers
- two-way radios.

Mobile wireless equipment can also transmit on unlicensed frequency bands such as the Industrial, Scientific, Medical (ISM) bands. ISM bands include 900 MHz, 2.4, 5.2, and 5.8 GHz and are commonly used for cordless phones and wireless data network equipment.

RF wireless transmitters can employ simple analog or more complex (and sometimes pulse-modulated) digital technology. Relating to output power, much of the mobile RF wireless equipment may be segmented into three broad categories:

1. The first category includes the Institute of Electrical and Electronics Engineers (IEEE) 802.11 family for wireless local area network (WLAN) technology (for example, IEEE 802.11 and 802.15), and most cordless phone-type systems that transmit constantly at relatively lower power (< 10 mW). This category has limited range because of RF output power, going from personal area networks (PAN) of up to 10 m diameter to longer-range, higher-power technology of a few hundred meters.

2. The second category consists of two-way radio and pager systems that transmit at a constant power that is higher by an order of magnitude or more (1-5 W). These transmitters can typically be used up to a distance of several miles, depending on the terrain and obstacles in the line-of-sight from transmitter to receiver.

3. The third category includes dynamically power-controlled equipment that can transmit at levels from a few milliwatts to 1-2 watts, depending on the existing network signal strength at that particular location and time.

The 802.11 family of standards refers to RF, over-the-air interface between a wireless client (such as a medical device) and a base station (or access point) or between two wireless clients. There are several specifications in the 802.11 family, including:

- **802.11** — applies to wireless LANs and provides 1 or 2 million bits per second (Mbps) transmission in the 2.4 GHz band using either frequency-hopping spread spectrum (FHSS) or direct sequence spread spectrum (DSSS).

- **802.11a** — an extension of 802.11 that applies to wireless LANs and provides up to 54 Mbps in the 5 GHz band. The 802.11a standard specifies an orthogonal frequency division multiplexing encoding scheme rather than FHSS or DSSS.
- **802.11b** (also referred to as 802.11 High Rate or Wi-Fi) — an extension to 802.11 that applies to wireless LANS and provides 11 Mbps transmission (with a fallback to 5.5, 2 and 1 Mbps) in the 2.4 GHz band. The 802.11b standard specifies only DSSS and allows wireless functionality comparable to Ethernet.
- **802.11g** — applies to wireless LANs and provides 20+ Mbps in the 2.4 GHz band.

A good summary of the specifications, output power, frequency bands, and international use of several applicable RF wireless technologies can be found in the recent ISO technical report TR 21730, Health Informatics – Use of mobile wireless communications and computing technology in healthcare facilities – Recommendations for the management of unintentional electromagnetic interference with medical devices (ISO/TR 21730:2005(E)). However, FDA recommends the reader be aware that RF wireless technology is dynamic and some specifications may change over time. We recommend you consult the FCC website for new specifications and updated information.

Appendix B: Reference Standards and Telecommunications Information

FDA recommends you refer to the FDA Recognized Consensus Standards Database at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm. Type "electromagnetic compatibility" in the title search for EMC standards that FDA recognizes for use in premarket applications.

The list below illustrates the national and international consensus and other standards related to EMC, medical device EMC, and telecommunications. FDA recognizes some of these standards for use in regulatory submissions. This list serves as a reference only and is not intended to present, substitute for, or represent specific suggestions or recommendations. We recommend you refer to FDA guidances for your specific device or situation as these guidances may supersede information in the standard.

Association for the Advancement of Medical Instrumentation (AAMI)
AAMI TIR No. 18-1997, Guidance on Electromagnetic Compatibility of Medical Devices for Clinical/Biomedical Engineers—Part 1: Radiated Radio-Frequency Electromagnetic Energy

ANSI/AAMI PC69:2000, Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators

ANSI/AAMI/IEC 60601-1-2:2001, Medical Electrical Equipment—Part 1–2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests. This is the U.S. version of the IEC 60601-1-2 standard (see IEC below)

American National Standards Institute (ANSI) Accredited Standards Committee C63 (ASC C63)
ANSI C63.18, American National Standard Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Radiated Electromagnetic Immunity of Medical Devices to Specific Radio- Frequency Transmitters
ANSI C63.19, American National Standard for Methods of Measurement of Compatibility between Wireless Communications Devices and Hearing Aids

Electrostatic Discharge Association (ESD Association)
ANSI/ESD-S20.20-1999, ESD Association Standard for the Development of an Electrostatic Discharge Control Program for – Protection of Electrical and Electronic Parts, Assemblies and Equipment (Excluding Electrically Initiated Explosive Devices)

European Telecommunications Standards Institute (ETSI)
I-ETS 300 220, Radio Equipment and Systems (RES); Short range devices Technical characteristics and test methods for radio equipment to be used in the 25 MHz to 1 000 MHz frequency range with power levels ranging up to 500 mW

ETS 300339, EMC and RSM (ERM); General EMC for radio communications equipment

ETS 300683, Radio Equipment and Systems (RES); EMC standard for Short Range Devices (SRD) operating on frequencies between 9 kHz and 25 GHz

ETSI EN 302 195-1, Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 9 kHz to 315 kHz for Ultra Low Power Active Medical Implants and Accessories; Part 1: Technical characteristics and test methods

Federal Communications Institute (FCC)
47 CFR Part 2, Frequency allocations and radio treaty matters; general rules and regulations

47 CFR Part 15, Radio frequency devices

47 CFR Part 18, Industrial, scientific, and medical equipment

47 CFR Part 95, Personal radio services (includes WMTS)

Information about these regulations can be found at the GPO website:

http://www.access.gpo.gov/nara/cfr/cfr-table-search.html. You may use this link for the guidance, and scroll down and click on the latest version of the title in question (for example, Title 47 [telecommunications] for FCC regulations). The latest version of Title 47 is at:
http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=200447.

International Electrotechnical Commission (IEC)
The IEC 60601 family specifies safety standards for medical electrical equipment. EMC is addressed in IEC 60601-1-2 and the IEC 60601-2-X standards for particular types of medical electrical equipment.

IEC 60601-1-2:2001 and Amendment 1:2004, Medical Electrical Equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests. This is a collateral standard to the second edition of IEC 60601-1. It specifies labeling that supplements Clause 6 of IEC 60601-1 and emissions and immunity requirements for Clause 36 of IEC 60601-1.

IEC 60601-2-X standards are for particular types of medical electrical equipment. Requirements of IEC 60601-2-X standards supersede those of IEC 60601-1 and of IEC 60601-1-2. Some IEC 60601-2-X standards specify higher immunity test levels or special test setups for EMC. Most have not yet been amended to reference the second (2001) edition of IEC 60601-1-2 and still reference the 1993 edition. Modifications to

IEC 60601-1-2 are specified in Clause 36. (Note: subclause numbers for similar provisions in IEC 60601-1-2:2001 are different from those in IEC 60601-1-2:1993.)

IEC 61326, Electrical equipment for measurement, control and laboratory use – EMC requirements

Institute of Electrical and Electronic Engineers (IEEE)
IEEE 1073.X, Health Informatics — Point-of-care medical device communication

IEEE 802.x standards

International Organization for Standardization (ISO) — Most ISO standards for medical electrical equipment reference clauses in IEC 60601-1, including Clause 36 and IEC 60601-1-2

ISO/TR 16056-1, Health informatics – Interoperability of telehealth systems and networks — Part 1: Introduction and definitions

ISO/TR 16056-2, Health informatics – Interoperability of telehealth systems and networks — Part 2: Real-time systems

ISO/TR 18307, Health informatics – Interoperability and compatibility in messaging and communication standards – Key characteristics

RTCA, Inc.
RTCA/DO-160D, Environmental Conditions and Test Procedures for Airborne Equipment