Radio Frequency Wireless Technology in Medical Devices

Guidance for Industry and Food and Drug Administration Staff

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Preface

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Radio Frequency Wireless Technology in Medical Devices

Guidance for Industry and Food and Drug Administration Staff

This guidance represents 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 guidance document to assist industry and FDA staff in identifying and appropriately addressing specific considerations related to the incorporation and integration of radio frequency (RF) wireless technology in medical devices. There has been rapid growth in medical devices that incorporate RF wireless technology due to the expansion of this technology. With the increasing use of RF wireless medical devices, continuing innovation and advancements in wireless technology, and an increasingly crowded RF environment, RF wireless technology considerations should be taken into account to help provide for the safe and effective use of these medical devices. This guidance highlights and discusses RF wireless technology considerations that can have an effect on the safe and effective use of medical devices. These considerations include the selection of wireless technology, quality of service, coexistence, security, and electromagnetic compatibility (EMC). Consideration of these areas can help provide reasonable assurance of safety and effectiveness for medical devices that incorporate RF wireless technology, and are supplementary to other device-specific guidances or guidelines.

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.

2. Scope

This guidance document addresses considerations that may affect the safe and effective use of medical devices that incorporate RF wireless technology (also referred to as wireless medical devices), including the selection of wireless technology, quality of service, coexistence, security, and EMC. These issues should be considered for all medical devices that incorporate RF wireless technology, such as Wireless Medical Telemetry Service (WMTS); Medical Device Radiocommunication Service (MedRadio) (including the former Medical Implant Communications Service (MICS)) as well as Medical Micropower Network (MNN) and Medical Body Area Network (MBAN); cellular communication chipsets; and RF identification (RFID) products. Such RF wireless technologies operate under a grant of certification and/or issuance of a license from the Federal Communications Commission (FCC).

This guidance also provides recommendations for information to be included in FDA premarket submissions for medical devices and device systems that incorporate RF wireless technology. Requirements by other agencies are not covered within this document, although we note that requirements established by the FCC may be applicable.

The recommendations in this guidance are intended for RF wireless medical devices including those that are implanted, worn on the body or other external wireless medical devices intended for use in hospitals, homes, clinics, clinical laboratories, and blood establishments. Both wireless induction-based devices and radiated RF technology device systems are within the scope of this guidance. The use of RF energy to generate images of the internal structures of the body such as in magnetic resonance imaging systems is outside the scope of this guidance document.

See Appendix A for a glossary of key terms associated with RF wireless technology and wireless medical devices that have been adapted from the IEC 60050-161 International Electrotechnical Vocabulary (IEV) and other sources.

3. Considerations for Design, Testing, and Use of Wireless Medical Devices

Designers and manufacturers of wireless medical devices should consider the ability of their devices to function properly in the intended use environments where other RF wireless technologies will likely be located. In the design, testing, and use of wireless medical devices, the correct, timely, and secure transmission of medical data and information is important for the safe and effective use of both wired and wireless medical devices and device systems. This is especially important for medical devices that perform critical functions such as those that are life-supporting or life-sustaining. For wirelessly enabled

medical devices, risk management should include considerations for robust RF wireless design, testing, deployment, and maintenance throughout the life cycle of the product.[1] Examples of potentially problematic wireless-related hazards and effects include:

- poorly characterized or poorly utilized wireless systems (e.g., wireless networks);
- lost, corrupted, or time-delayed transmissions, and degradations in wireless transmissions including when caused by competing wireless signals or electromagnetic interference (EMI) to the medical device or its wireless transmissions;
- lack or compromise of wireless security; and
- potential misuse of a wireless medical device because of lack of or inadequate instructions for use.

As part of a comprehensive quality system under 21 CFR Part 820, medical device manufacturers must manage risks including those associated with RF wireless technology that is incorporated into the medical device or device system. ISO 14971 *Second edition 2007-03-01 Medical devices—Application of risk management to medical devices* can be a useful tool in risk analysis and risk management.[2] Because there are risks associated with RF wireless systems, we recommend that you carefully consider which device functions should be made wireless and which device functions should employ wired connectivity.

FDA recommends that you address known safety issues involving RF wireless technologies early in the device design and development process. Safety issues might be discovered during the design and development process for which risk mitigation measures might be necessary to ensure an overall acceptable level of risk. FDA also recommends that risk acceptability criteria be based on information about the device and its intended use, including, but not limited to, applicable standards, accepted design practices, and experience with similar devices. For example, FDA recommends that you use reports of EMI-related events and other relevant experience when estimating probability of occurrence as part of risk analysis. In addition, where multiple alarms are incorporated into a device or device system via wireless links, we recommend that you address priorities for accessing the wireless system, and priorities related to the function of the wireless technology itself.

In validating the design of your wireless medical device under 21 CFR 820.30(g), you must include risk analysis of RF wireless communications and control functions as part of your design validation. Because it is possible for an electromagnetic disturbance (EMD) to affect important medical device functions, mitigation measures for some risks could aid the device operator in recognizing a hazardous situation and taking action to prevent harm. For

[1] Risk management is a key component of the quality system, and includes risk analysis, which is part of the design control requirements under the quality systems regulation. 21 CFR 820.30(g).
[2] ISO 14971 is on FDA's list of recognized consensus standards, which is available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=30268.

example, design validation might reveal that steps to reestablish an RF wireless connection such as re-initialization could compromise safety under some use conditions.

When considering possible adverse outcomes, you should also consider risks to other devices and patients whose wireless connections might suffer from, or be the source of, interference. In addition, you should consider the potential impact of unintended interference and purposeful attempts to disrupt a wireless medical device or an associated device network's functionality.

The following considerations should be appropriately tailored to the selected RF wireless technology, and the intended use and use environments for your medical device. The following discussion of these considerations includes information dealing with general and design considerations, risk management, verification and validation, and information shared with users. Note that access to information (e.g., user manual, other device labeling) concerning these key considerations plays an important role in users being able to properly set up, use and maintain medical devices and device systems with wireless technology.

a. Selection and performance of wireless technology

When selecting the type(s) of wireless technology, it is vital to determine and understand the medical device functions that are to be wirelessly enabled and the intended use of the medical device. The medical device functions and intended uses should be appropriately matched with the wireless technology's capabilities and expected performance. In addition, issues relating to the integrity of data transmitted wirelessly (including latency and throughput, detection, correction, and corruption control and/or prevention) and safety-related requirements of your device should be considered. Potential risks that can affect consistent and timely wireless medical device functions include data corruption or loss and interference from simultaneous transmitters in a given location, which can increase latency and transmitted signal error rates. For wireless medical devices and device systems, error control processes should be incorporated to assure the integrity of data transmitted wirelessly and to manage potential risks related to maximum delay of data transfer. Parameters such as bit error rate, packet loss, and signal-to-noise ratio are useful tools in assessing and assuring data integrity and timeliness of data transmission.

In addition, the device performance and specifications related to the wirelessly enabled medical device functions should be considered in choosing the appropriate RF wireless technology (e.g., WMTS, IEEE 802.11) and RF frequency of operation. It is important to note that many medical devices are authorized to operate as unlicensed devices (under Part 15 of the FCC rules[3]) in the industrial, scientific, and medical (ISM) frequency bands (e.g., 2400-2493.5 MHz), and as such, are not entitled to interference protection. There is

[3] For additional information on frequency bands and use, please refer to http://www.fcc.gov/encyclopedia/accessing-spectrum and http://www.fcc.gov/encyclopedia/rules-regulations-title-47.

a potential for interference in this frequency band because it is already heavily used by many other communications and industrial products. In many cases, RF wireless medical devices and transmission streams can incorporate technology (e.g., frequency hopping protocols, correction protocols) to minimize effects of interference that may lead to data errors or corruption. Also, to help protect against EMI to other medical devices in the vicinity, FDA recommends that wireless medical device manufacturers limit the RF output of their devices to the lowest power necessary to reliably accomplish the intended functions.

Consideration should be given to any limitations or restrictions for proper operation and RF wireless performance (e.g., alarms, back-up functions, alternative modes of operation) when the RF wireless link is lost or corrupted. In addition, worldwide frequency band allocation and international compatibility is critical to the operations of RF wireless devices, and should be considered in the design and development of wireless medical devices.

When choosing a RF wireless frequency band or a commercial wireless radio component, FDA recommends that you consider:

- International availability and band allocation (e.g., applicable International Telecommunication Union Radiocommunication Sector (ITU-R)[4] recommendations) for medical devices because medical devices serve patients located in multiple geographic locations and patients may change their geographic locations.
- Whether your device needs to have primary or secondary radio service classification, which depends upon the wireless frequency band you choose.
- Incumbent users of the selected and adjacent bands, if any, and how they can impact a medical device's operation.
- Applicable interference mitigation techniques if you are planning to use a shared RF wireless frequency band.
- For implantable and body-worn medical devices, tissue propagation characteristics and specific absorption rate as appropriate.

When considering commercial off-the-shelf RF wireless components or systems that conform to industry standards (such as IEEE 802.11 standards), medical device manufacturers should take into account that some equipment might not have been adequately tested or qualified to address the needs and risks for use in medical devices. This is because such equipment may conform to standards that are not written specifically for medical devices. Under the quality system regulation, procedures and controls must be established for wireless medical devices and their components, including components

[4] http://www.itu.int/en/ITU-R/Pages/default.aspx

that are purchased and included as part of the device or device system, to ensure that the device and its components conform to specified design requirements related to the RF wireless considerations noted above.[5]

b. Wireless Quality of Service

Wireless Quality of Service (QoS) refers to the necessary level of service and performance needed for the wireless functions of the medical device. While the QoS of cellular telephone networks might be acceptable for voice communication, it might not be sufficient for certain medical functions. Connections lost without warning, failure to establish connections, or degradation of service can have serious consequences, especially when the medical device relies heavily on the wireless connection. Such situations can compromise the wireless transmission of high-priority medical device alarms, time-sensitive continuous physiological waveform data, and real-time control of therapeutic medical devices (such as wireless footswitches).

If the wireless medical device will be part of a network, wireless QoS should be carefully considered in conjunction with the intended use of the wireless medical device. The following should be assessed: acceptable latency, acceptable level of probability for loss of information within the network, accessibility, and signal priorities of the network.

When the network is chosen or designated, FDA recommends use of a risk management approach to deployment, security, and maintenance of the network's QoS. Depending on the intended use of the device, additional failure modes may need to be considered. Once failure modes and associated risks are identified, we recommend a justification of acceptable risk, or testing or other measures to demonstrate appropriate risk mitigation.

c. Wireless coexistence

A key factor affecting a wireless medical device's performance is the limited amount of RF spectrum available, which can result in potential competition among wireless technologies for simultaneous access to the same spectrum. Because conflicts among wireless signals can be expected, most wireless communication technologies incorporate methods to manage these conflicts and minimize disruptions in the shared wireless environment. The selection of RF wireless operating frequency and modulation should take into account other RF wireless technologies and users that might be expected to be in the vicinity of the wireless medical device system. These other wireless systems can pose risks that could result in medical device signal loss or delay that should be considered in the risk management process. To address this issue, FDA recommends that you address your device's environmental specifications and needs, including:

[5] *See, e.g.,* 21 CFR 820.30(f) (design verification); 21 CFR 820.30(g) (design validation); 21 CFR 820.50 (purchasing controls); and 21 CFR 820.80 (acceptance activities).

- Associated sources of EMD expected in specific known use environments, and
- Co-channel and adjacent channel interference from medical devices and other users of the RF band.

If the RF wireless medical device is expected to be used in proximity to other RF wireless in-band (i.e., the same or nearby RF frequency) sources, FDA recommends addressing such risks through testing for coexistence of the device wireless system in the presence of the number and type of in-band sources expected to be in proximity to the device. Depending upon the wireless medical device, this should also include multiple units of the subject device operating in the same vicinity, such as when patients are sitting adjacent to one another in a waiting room. Once failure modes and associated risks are identified, we recommend a justification of acceptable risk, or testing or other measures to demonstrate appropriate risk mitigation.

d. Security of wireless signals and data

Security of RF wireless technology is a means to prevent unauthorized access to patient data or hospital networks and to ensure that information and data received by a device are intended for that device. Authentication and wireless encryption play vital roles in an effective wireless security scheme. While most wireless technologies have encryption schemes available, wireless encryption might need to be enabled and assessed for adequacy for the medical device's intended use. In addition, the security measures should be well coordinated among the medical device components, accessories, and system, and as needed, with a host wireless network. Security management should also consider that certain wireless technologies incorporate sensing of like technologies and attempt to make automatic connections to quickly assemble and use a network (e.g., a discovery mode such as that available in Bluetooth™ communications). For certain types of wireless medical devices, this kind of discovery mode could pose safety and effectiveness concerns, for example, where automatic connections might allow unintended remote control of the medical device.

FDA recommends that wireless medical devices utilize wireless protection (e.g., wireless encryption,[6] data access controls, secrecy of the "keys" used to secure messages) at a level appropriate for the risks presented by the medical device, its environment of use, the type and probability of the risks to which it is exposed, and the probable risks to patients from a security breach. FDA recommends that the following factors be considered during your device design and development:

- Protection against unauthorized wireless access to device data and control. This should include protocols that maintain the security of the communications while

[6] At the time of publication of this guidance, this included WiFi Protected Access (WPA2) for IEEE 802.11 technology.

avoiding known shortcomings of existing older protocols (such as Wired Equivalent Privacy (WEP)).

- Software protections for control of the wireless data transmission and protection against unauthorized access.

Use of the latest up-to-date wireless encryption is encouraged. Any potential issues should be addressed either through appropriate justification of the risks based on your device's intended use or through appropriate design verification and validation.

For more information on this topic, see FDA's draft guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices." (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm356186.htm). FDA's draft guidance represents FDA's proposed approach on this topic.

e. EMC of the wireless technology

FDA recommends that EMC be an integral part of the development, design, testing, and performance for RF wireless medical devices. This should include consideration of applicable telecommunications standards and regulations and the potential for device RF emissions that might cause EMI with other equipment. In addition, RF wireless technology (by itself and in conjunction with the medical device) would also need to meet applicable FCC requirements. Risk management activities should include using risk analysis to identify any potential issues associated with EMC and determining risk acceptability criteria based on information about the device and its intended use, including foreseeable misuse, sources of environmental EMD (e.g., radio transmitters, computer RF wireless equipment), and the potential for RF emissions to affect other devices.

EMC testing should include tests focused on the medical device wireless functions and technology. Some voluntary consensus standards such as the FDA-recognized[7] consensus standard IEC 60601-1-2 "Medical Electrical Equipment – Part 1-2: General requirements for safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests" contain an exemption from the electromagnetic immunity provisions in the "exclusion band" (passband) where the medical device's RF wireless receiver or transmitter operates. Consequently, such standards do not adequately address whether the wireless communications will operate properly in the presence of in-band EMD (e.g., other RF emissions overlapping the frequency band utilized by the medical device wireless signals). Therefore, the medical device's wireless

[7] For a current list of FDA-recognized consensus standards, see the Recognized Consensus Standards Database at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

communication(s) should be actively transmitting while testing for susceptibility during all EMC immunity testing.

EMC considerations are also covered in other standards that might be helpful for medical devices that incorporate RF wireless technology. For example, EMC considerations for active implantable medical devices are covered under documents such as the ISO 14708-1 standard (see Appendix B).

Adequate information for the user is especially important if the device might be used in high electric or magnetic field strength environments, and particularly if the device cannot be made to function as intended in these environments. To help ensure safe and effective use of your device, FDA recommends that the information for users include the following:

- Conformance to the IEC 60601-1-2 standard or other appropriate standards, and
- EMC susceptibilities discovered during testing, and mitigations such as recommended separation distances from other devices or EMD sources.

The IEC 60601-1-2 standard specifies that certain information based upon the EMC testing be included in "accompanying documents." This information includes a summary of the test findings and additional EMC-related information such as classification of the electrical power supply and use conditions.

f. Information for proper set-up and operation

To help assure proper set-up, configuration, and performance of the wireless medical device, appropriate information should be provided to users. The following are suggested items to consider as part of this information:

- The specific RF wireless technology type (e.g., IEEE 802.11b), characteristics of the modulation, and effective radiated RF power.
- Specification of each RF frequency or frequency band of transmission and the preferred frequency or frequency band (if applicable), and specification of the bandwidth of the receiving section of the equipment or system in those bands.
- Appropriate FCC labeling.
- A warning that other equipment could interfere with the medical device or device system, even if the other equipment complies with CISPR[8] emission requirements.

[8] Comité Internationale Spécial des Perturbations Radioelectrotechnique (International Special Committee on Radio Interference). CISPR electromagnetic emission standards are referenced in the IEC 60601-1-2 standard. See Appendix B.

- Information about the needed quality of service and security for the wireless technology.
- Functions and performance of the wireless data transmissions including data throughput, latency, and data integrity.
- Information about any limitations on the number, output power, or proximity of other in-band transmitters used in the vicinity that might adversely impact a device's system operation.
- Information for the user to understand the RF wireless technology's capabilities and be able to recognize and address issues that might arise. For devices with intended use locations that are in complex RF wireless environments and consist of multiple wireless products, this should include assessment and management of the RF wireless transmitters and their use in the vicinity including transmitters both inside and outside the facility.
- Information for the user to understand the implications and limitations of using RF wireless technology outside the United States, where allocations and technical parameters may be different, possibly affecting the functioning of the device.

g. Considerations for maintenance

Device Life Cycle - FDA recommends that you continue to manage the risks associated with the use of wireless technology described above for the entire life cycle of your device. Your procedures for implementing corrective and preventive action must include, among other things, analyses for possible trends in nonconformance information and complaints, such as reports of failures, which could include erratic or unexpected behavior of the medical device.[9] Examples of such behavior include reprogramming of stimulation devices, commands missed or misinterpreted by operating room controllers, unexplained inconsistencies of an infusion pump, and failure to activate alarm signals in alarm conditions.

Because electromagnetic emissions and exposure can vary significantly with various structures, materials, and RF wireless emitter sources in the vicinity, FDA recommends that in analyzing failure trends, you consider factors such as location, user application, and repeat component failures. Potential problems include:

- Additional events that may have contributed to the EMI or disruption of wireless technology resulting in inappropriate or unnecessary diagnostic procedures or interventions;
- Additional equipment used in conjunction with the device;
- Environmental conditions that might have contributed to the event; and

[9] 21 CFR 820.100(a).

- Repeated device failures at the same facility or in other geographic areas.

If you identify a failure or malfunction of an RF wireless function, you must investigate the cause and take action(s) to correct the problem and prevent its recurrence.[10] You must analyze production and repair records and other sources of quality data to determine the cause of the nonconformance.[11] Any corrective action and preventative action taken must be verified or validated to ensure that such action is effective and does not adversely affect the finished device.[12] FDA further recommends that you assess any product lines that use similar designs or are subject to the same environment to determine whether corrective and preventive actions are needed for those products.

Servicing - When servicing electrically powered medical devices, FDA recommends that you maintain the integrity of RF wireless functions and design elements intended to ensure EMC. Care should be taken to ensure EMI protection is 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. In addition, FDA recommends that you do not paint metal surfaces that are intentionally left bare for RF shielding continuity. To reduce EMI susceptibility as electronic equipment ages, we recommend that you clean connector contacts that might have oxidized because oxidized contacts can act as semiconductors.

4. Recommendations for Premarket Submissions[13] for Devices that Incorporate RF Wireless Technology

When preparing a premarket submission for a device that incorporates RF wireless technology, FDA recommends that you include the following information, as appropriate, for your specific medical device.

[10] 21 CFR 820.100(a).
[11] 21 CFR 820.100(a).
[12] 21 CFR 820.100(a).
[13] This guidance document applies to the following premarket submissions for devices: premarket notifications (510(k)), *de novo* petitions, premarket approval applications (PMA), product development protocols (PDP), humanitarian device exemption (HDE) applications, and Biologics License Applications (BLA). Manufacturers may also consider applying the recommendations provided in this guidance, as appropriate, to investigational device exemption (IDE) applications and investigational new drug (IND) submissions to CBER related to BLA devices.

a. Description of device

In order to facilitate the review of the submission, the device description for a wireless medical device should include the following information specific to the wireless technology and functions:

- A description of the wireless technology and functions, and the intended use of the medical device and intended use environment. This should include the form and specific type of wireless technology that is incorporated into the device (e.g., IEEE 802.11b, IEEE 802.15 Bluetooth™), RF frequencies and maximum output powers, range, and where and how the wireless technology is to be used.

- A description of how the design of the device's wireless function(s) assures timely, reliable, accurate, and secure data and wireless information transfer. This includes the wireless QoS needs and security measures.

- If wireless technology is used for transmission, reception, or process involving alarm signals, a description of the alarm signal, its priority, and how the RF wireless-related risks are managed and, if appropriate, mitigated.

- Identify whether other wireless products or devices are able to make a wireless connection to the device. If so, summarize the products or devices and their function and how the subject medical device functions are protected from adverse effects of such connections to the other products or devices.

b. Risk-based approach to verification and validation

1. Wireless Quality of Service – The submission should include information to describe the wireless QoS needed for the intended use and use environment of the medical device. This includes addressing any risks and potential performance issues that might be associated with data rates, latency, and communications reliability as described in Section 3-b.

2. Wireless coexistence – Any risks and potential performance issues that might be associated with wireless coexistence in a shared wireless environment should be addressed via testing and analysis with other wireless products or devices that can be expected to be located in the wireless medical device's intended use environment. See Section 3-c. The information addressing coexistence should include the following:

- A summary of the coexistence testing, set-up, findings, and analysis.

- The wireless products (interferers) that were used in the coexistence testing, and their wireless RF frequencies, maximum output powers, and separation distances from the device.

- The specific pass/fail criteria for this testing.

- How the device and wireless functions were monitored during the testing and determined to meet the pass/fail criteria.

- If it is reasonable to expect multiple units of the subject wireless medical device to be used in the same vicinity, the information should also address how the association and security between devices is established and maintained to prevent cross-talk among the devices.

3. Security of wireless signals and data - The submission should identify any risks, potential performance issues, and, if appropriate, risk mitigation measures that might be associated with wireless security. The information should include the specific measures needed to protect against unauthorized wireless access to the medical device control or data and to ensure that information and data received by a device are intended for that device. For wireless technology with a discovery mode or similar active connection mode, specific information should be included addressing the discovery mode and how outside users can be prevented from sensing or connecting to the medical device. See Section 3-d.

4. EMC of the wireless technology – Information should be provided about how EMC has been addressed for the device and all wireless functions. However, as mentioned in section 3-e., the widely used IEC 60601-1-2 consensus standard does not at present adequately address wireless technology EMC. Therefore, testing, analysis, and appropriate mitigation might be necessary to adequately address any risks or potential performance issues that might be associated with the EMC of the wireless medical device. If modifications to the medical device were made to pass any EMC testing, please include a description of, and justification for, the modifications.

c. Test data summaries

FDA recommends that the final RF wireless and EMC testing[14] and results be summarized in your premarket submission, which should contain the following information:

- Description of the tests performed (e.g., RF wireless performance, EMC immunity and emissions, test levels or limits) and the protocol used;

[14] By final testing we refer to testing performed on the final integrated product.

- Reference 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 the significance of these modes;
- Specific pass/fail criteria for the testing such as specific device-related acceptability criteria for each device mode or function tested. These criteria should include the following:
    - Specific device functions that should not degrade (such as CPU failure);
    - Device functions that may degrade (such as display fluctuation); and
    - Device recovery from degradation (such as after removal of the electrostatic discharge (ESD)).
- If modifications were made to the medical device in order to pass testing, a statement that all modifications will be incorporated into all final production units.

d. Labeling related to wireless medical devices

To facilitate the safe and effective use of the wireless medical device, the proposed labeling should include risk mitigation measures that address RF wireless issues and any precautions users should take. You should be aware that while labeling statements, such as warnings, may be helpful, they are not a substitute for risk mitigation measures or other design control activities, and are typically not adequate to prevent adverse events.

FDA recommends that the following information be included in the device labeling:

- A summary of the medical device wireless functions and specific wireless technology incorporated into the medical device or device system including equipment or system specifications (e.g., the standard IEEE 802.11 b/g, IEEE 802.15.4 Bluetooth™ class II);
- A summary of the operating characteristics of the wireless technology, effective RF radiated power output and operating range, modulation, and bandwidth of receiving section;
- A brief description of the wireless QoS needed for safe and effective operation;
- A brief description of the recommended wireless security measures such as the WPA2 wireless encryption for IEEE 802.11 technology;

- Information addressing wireless issues and what to do if problems occur;
- Information about any wireless coexistence issues and mitigations. This can include precautions for proximity to other wireless products, and specific recommendations for separation distances from such products;
- Appropriate EMC and telecommunications standards compliance and test results summary;
- Appropriate RF wireless communications information such as those required by FCC rules; and
- Warnings about possible effects from RF sources in the vicinity of the device (e.g., electromagnetic security systems, cellular telephones, RFID or other in-band transmitters).

In addition, FDA recommends that your labeling also include all of the information as outlined in the appropriate reference standards (e.g., IEC 60601-1-2). You should also consider any other appropriate FDA guidances or special controls guidelines applicable to your device for additional labeling information.

Appendix A: Glossary for Wireless Medical Devices and Device Systems

The following definitions were adapted from IEC 60050-161 International Electrotechnical Vocabulary (IEV), IEEE Standard 802.15.2™-2003, the IEEE Standard 11073-00101™ - 2008, and other sources.[15]

Data integrity — Assurance that transmitted files are not deleted, modified, duplicated, or forged without detection.

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

Electromagnetic disturbance (EMD) — any electromagnetic phenomenon that might degrade the performance of an equipment, such as medical devices or any electronic equipment. Examples include power line voltage dips and interruptions, electrical fast transients (EFTs), electromagnetic fields (radio frequency 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. Note: *Disturbance* and *interference* are cause and effect, respectively.

Electrostatic discharge (ESD) — the rapid transfer of an 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 can 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 that interconnect 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

[15] Sources include: Federal Standard 1037C Telecommunications: Glossary of Telecommunications Terms.

carrying information and unintentional emissions associated with electrically powered equipment such as motors, power supplies, and computer components.

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, which is also known as transfer delay.

Quality of service (QoS) — the necessary 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-frequency and the infrared portions, and is useful for radio transmission. 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, which causes degradation of the reception of a wanted signal by a radio-frequency *electromagnetic disturbance*.

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 might be implemented wirelessly include data transfer, device control, programming, power transmission, remote sensing and monitoring, and identification.

Security — a collection of services, policies, mechanisms, and controls that provides information confidentiality, integrity, and availability by restricting unauthorized parties from accessing, manipulating, or leveraging particular system resources. Some security services might include data encryption, data integrity-checking, user and device authentication, and non-repudiation.

Specific absorption rate (SAR) — a measure of the rate at which energy is absorbed by the body when exposed to an RF electromagnetic field. It is defined as the power absorbed per mass of tissue and has units of watts per kilogram. SAR is usually averaged either over the entire body, or over a small sample volume (typically 1 g or 10 g of tissue).

Susceptibility — the potential for equipment (including medical devices) to respond to an *electromagnetic disturbance*. The inability of a device, equipment or system to perform without degradation in the presence of an *electromagnetic disturbance.* Note: *Susceptibility* is a lack of *immunity*.

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 might or might not be using the same set of rules.

Appendix B: Reference Standards and Information

FDA recommends that you refer to the FDA Recognized Consensus Standards Database at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm, and type "electromagnetic compatibility" in the title search for EMC standards that FDA recognizes for use in premarket submissions. For information on recognized consensus standards, see the guidance document "Frequently Asked Questions on Recognition of Consensus Standards," http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm074973.htm.

The list below illustrates national and international consensus standards and other standards, and documents and information related to EMC, medical device EMC, and telecommunications. FDA recognizes some of these standards for use in regulatory submissions. However, this list serves as a reference only and is not intended to substitute for or represent specific suggestions or recommendations. We recommend that you refer to FDA guidances or special controls guidelines applicable to your specific device.

Association for the Advancement of Medical Instrumentation (AAMI)

AAMI TIR No. 18-2010, Guidance on electromagnetic compatibility of medical devices in healthcare facilities

ANSI/AAMI PC69:2007, Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators

ANSI/AAMI/IEC 60601-1-2:2007/ (R) 2012, Medical Electrical Equipment—Part 1–2: General requirements for basic safety and essential performance – 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 C63.4:2009, American National Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz

ANSI C63.10:2009, American National Standard for Methods for Testing Unlicensed Wireless Devices

ANSI C63.18:1997, 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 C63.19:2007, American National Standard Methods of Measurement of Compatibility between Wireless Communications Devices and Hearing Aids

Electrostatic Discharge Association (ESD Association)

ANSI/ESD S20.20-2007, 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)

Federal Communications Commission[16]

Code of Federal Regulations, Title 47 – Telecommunications, Chapter I - Federal Communications Commission, Subchapter A – General

- Part 2 – Frequency Allocations and Radio Treaty Matters; General Rules and Regulations
- Part 15 – Radiofrequency Devices
- Part 18 – Industrial, Scientific, and Medical Equipment

Subchapter D - Safety and Special Radio Services

- Part 95 – Personal Radio Services

International Electrotechnical Commission (IEC)

The IEC 60601 family specifies safety standards for medical electrical equipment. EMC is addressed in IEC 60601-1-2, and IEC 60601-2-X provides standards for particular types of medical electrical equipment.

IEC 60601-1-2:2007, Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance– Collateral standard: Electromagnetic compatibility – Requirements and tests. This is a collateral standard to the third edition of IEC 60601-1. The third edition of IEC 60601-1-2 was published in 2007 and contains essentially the same

[16] For further information about these or other FCC requirements, please refer to http://www.fcc.gov/encyclopedia/rules-regulations-title-47 .

information that was in the second edition IEC 60601-1-2:2001 and Amendment 1:2004, reformatted according to the third edition of the IEC 60601-1 standard. Emissions and immunity requirements in the third edition IEC 60601-1 are specified under Clause 17.

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 IEC 60601-1-2. Some IEC 60601-2-X standards specify higher immunity test levels or special test setups for EMC. Some might not have been amended yet to reference the third (2007) edition of IEC 60601-1-2 and might still reference an earlier edition. Modifications to IEC 60601-1 for EMC are specified in Clause 17 in the IEC 60601-1-2:2007 edition and Clause 36 in earlier editions. (NOTE: Subclause numbers for similar provisions in IEC 60601-1-2:2007 are different from those in earlier editions.)

IEC 61326-1:2005, Electrical equipment for measurement, control and laboratory use – EMC requirements - Part 1: General requirements. Edition 2.0 was published in 2012.

IEC 61326-2-1:2005, Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-1: Particular requirements - Test configurations, operational conditions and performance criteria for sensitive test and measurement equipment for EMC unprotected applications. Edition 2.0 was published in 2012.

IEC 61326-2-6:2005, Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment. Edition 2.0 was published in 2012.

IEC 60050-161:1990, International Electrotechnical Vocabulary – Chapter 161: Electromagnetic compatibility. Amendment 2 was published in 1998. IEV online: http://www.electropedia.org/

IEC TR 80001-2-3: 2012, Application of Risk Management for IT-Networks Incorporating Medical Devices – Part 2-3: Guidance for wireless networks

Institute of Electrical and Electronic Engineers (IEEE)

P11073-00101™-2008 - Guide for Health Informatics–Point-of-Care Medical Device Communication–Guidelines for the Use of RF Wireless Technology. There are several standards under the IEEE 11073 family that address health informatics point-of-care medical device communications and provide useful information.

IEEE Std 802.15.2™-2003 IEEE Recommended Practice for Information Technology—Telecommunications and Information Exchange between Systems— Local and Metropolitan Area Networks— Specific Requirements Part 15.2: Coexistence of Wireless Personal Area Networks with Other Wireless Devices Operating in Unlicensed Frequency Bands.

International Organization for Standardization (ISO)

Most ISO standards for medical electrical equipment reference clauses in IEC 60601-1, including Clause 17 (previously 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

ISO 14708-1, Implants for surgery – Active implantable medical devices – Part 1: General requirements for safety, marking, and for information to be provided by the manufacturer

ISO 14708-2, Implants for surgery — Active implantable medical devices — Part 2: Cardiac pacemakers

ISO 14708-3, Implants for surgery - Active implantable medical devices - Part 3: Implantable neurostimulators.

ISO 14708-4, Implants for surgery — Active implantable medical devices — Part 4: Implantable infusion pumps

ISO 14971 Second edition 2007-03-01 Medical devices — Application of risk management to medical devices

ISO 14117, Active implantable medical devices – Electromagnetic compatibility – EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices.

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: 2007(E)).

RTCA, Inc.

RTCA/DO-160G, Environmental Conditions and Test Procedures for Airborne Equipment