April 2, 2007

Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane Rm 1031
Rockville, MD 20852

Docket No. 2006D-0504: Draft Guidance for Industry and FDA Staff - Radio-Frequency Wireless Technology in Medical Devices

To Whom IT May Concern:

Hospira Worldwide, Inc. (Hospira) is pleased to have this opportunity to submit our comments in response to the FDA Docket No. **2006D-0504**: Draft Guidance for Industry and FDA Staff - Radio-Frequency Wireless Technology in Medical Devices. As a manufacturer of medical devices and more specifically, wireless capable infusion systems, Hospira requests FDA to provide clarity to certain parts of sections 4, 6, and 7 of the guidance document: Draft Guidance for Industry and FDA Staff - Radio-Frequency Wireless Technology in Medical Devices prior to final issuance. Hospira has provided comments in italics after each pertinent section on pages 3, 4, 7 and 9 of this document..

Background:

Hospira is a global specialty medication delivery company dedicated to Advancing Wellness™ by developing, manufacturing and marketing products that improve the productivity, safety and efficacy of patient care. Created from the core global hospital products business of Abbott Laboratories in April 2004, Hospira has a 70-year history of service to the hospital industry and is building its future from a strong foundation as one of the largest manufacturers of hospital products in the United States. Hospira has established long-standing customer relationships that span the "continuum of care" (hospitals, alternate site facilities, home healthcare providers and long-term care facilities). Hospira has a leading position in the manufacture and supply of a broad range of hospital products including:

- Specialty injectables
- Medication delivery systems (including electronic infusion pumps)
- Infusion therapy solutions/supplies
- Critical care devices

Currently, Hospira globally manufacturers medical devices that will be impacted by a Guidance for Industry that pertains to Radio-Frequency Wireless Technology in Medical Devices.

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 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.

Response:

Hospira requests that FDA clarifies the requirements it is considering for operation in the presence of an in-band EMD to insure adequate testing is performed prior to premarket submission or product release to market.

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.

Response:

Are the wireless technologies identified above considered inclusive standard technologies that should be used as a testing baseline for operational purposes? Furthermore, as technology continues to evolve will sponsors need to adapt to new bandwidth requirements for products currently on market?

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.

Response:

Latency can be dependent on a customer or user site network and therefore may be challenging to achieve consistent quality of service. What is FDA's position of facility uniformity or responsibility to achieve this operational need?

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.

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

Response:

Is it FDA's position that sponsors should evaluate the RF environmental operational capabilities of their devices in all of the scenarios listed above? Should radiological equipment be included in this evaluation?

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:

- 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.

Response:

Does FDA's definition of data security mean unauthorized manipulation or overriding of operational device functions and access to patient or facility information?

Thank you for the opportunity to provide comments to this proposed guidance. Please contact me if I can provide any additional information.

Sincerely,

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