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April 2, 2007

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: **Docket No. 2006D-0504**

Dear Sir or Madam:

Attached are comments from LifeScan, Inc. regarding Docket No. 2006D-0504 entitled:

Draft Guidance for Industry and Food and Drug Administration
Staff: Radio-Frequency Wireless Technology in Medical Devices

If you have any questions about these comments, please contact me at the telephone number above.

Thank you for considering our comments.

Sincerely yours,

A handwritten signature in cursive script that reads "John E. Hughes". The signature is written in dark ink and is positioned above the typed name.

John E. Hughes
Sr. Manager,
Regulatory Affairs

Docket No. 2006D--0504

Comments from LifeScan, Inc.

Draft Guidance for Industry and FDA Staff Radio-Frequency Wireless Technology in Medical Devices

DRAFT GUIDANCE

Page 7 Performance of Wireless Functions

Current Text

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.

Proposed Text

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, list any standards followed in the design and testing of the device, and your results demonstrating the wireless functions will operate safely and effectively in the intended use environment.

Rationale

Requesting identification in the submission of relevant standards helpful in addressing issues, such as some of the ANSI standards addressing specific aspects of RF communication technology, further informs the user community for this guidance.

Page 7/8 Wireless Coexistence

Current Text

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.

Proposed Text

Modulation and synchronization techniques are among the many technologies that allow devices to coexist in the same frequency spectrum and geographic location. You should include wireless coexistence concerns in your risk management process and use the re-

sults to help address the selection of an appropriate RF wireless communication technology during your design and development process.

Rationale

Given their importance in mitigation of wireless coexistence problems, explicit mention of modulation and synchronization techniques in this section seems warranted. Also, a logical process approach would be to incorporate these concerns into the risk analysis and use the output to help guide the selection of an appropriate technology.

p. 8/9 Wireless quality of service

Current Text

No change.

Proposed Text

Add the following paragraph.

The potential for serious adverse outcomes as a result of connection loss mean that the design and development process should include suitable mitigations (multiple antennas with appropriate discrimination techniques, spread spectrum multi-channel encoding, etc.).

Rationale

Potential mitigations are presented as guidance in some sections of this discussion of concerns about medical device RF wireless communication yet omitted here. It seems appropriate to provide some discussion of possible approaches in this section as well.

p. 9 Integrity of data transmitted wirelessly

Current Text

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).

Proposed Text

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, data/communication authentication, secure protocols, etc.).

Rationale

We suggest expansion of the guidance to indicate that multiple approaches to the problems of interference, data errors or corruption are available.

p. 9 Security of data transmitted wirelessly and wireless network access

Current Text

No change.

Proposed Text

Add the following sentence.

Data encryption, multiple carriers, customized encoding or modulation are among the design approaches which can be considered to prevent or minimize unauthorized access in applications where this is a concern.

Rationale

Some sections in this discussion of concerns address mitigation approaches, others do not. The document would have enhanced usefulness if it indicated in general terms that solutions exist and guided the reader toward these possible solutions.

p. 9 EMC

Current Text

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.

Proposed Text

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” provide electromagnetic emissions and immunity requirements for medical electrical equipment.

As discussed in “Performance of wireless functions” above, RF receivers and transmitters are exempt in this standard from electromagnetic immunity provisions in their passband although modulation or encoded synchronization techniques exist which can enhance RF

device immunity. 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.

Rationale

An editorial comment is present recommending elimination of unnecessary second reference to IEC 60601-1-2:2001 in the current text. We have proposed reformatting of existing content to link the problem directly to the FDA recommendation to document the testing that was done to address electromagnetic immunity. In addition, some reader guidance on possible approaches is suggested.

p. 10 Examples of problems reported with RF wireless medical devices

Current Text

None

Proposed Text

Add the following sentence at the beginning of the section.

The following reports illustrate the problems, probably caused by a lack of secure communications and/or a lack of authentication, which can arise with RF wireless devices.

Rationale

Characterization of the probable basis for the problems reported would be instructive guidance if added.

p. 11 5. Risk Management for RF Wireless Devices: General Concepts

Current Text

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.

Proposed Text

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

- intended use

- foreseeable misuse
- data integrity
- communication integrity
- sources of environmental EMD (e.g., radio transmitters, computer RF wireless equipment, other wireless communication equipment and medical devices)
- potential to affect other devices.

Rationale

The integrity of data and of communication is especially important when RF wireless techniques are incorporated into medical devices. They should be specifically mentioned when identifying factors relative to RF wireless to incorporate into the risk management program.

p. 11 5. Risk Management for RF Wireless Devices: General Concepts

Current Text

For example, we recommend you use reports of EMI-related events and other relevant experience when estimating probability of occurrence.

Proposed Text

For example, we recommend you use reports of EMI-related events and other relevant experience as well as anticipating the probable impact of the use environment when estimating probability of occurrence.

Rationale

Limiting the factors considered to existing problem reports when estimating probability of occurrence will probably result in unrealistically low estimates given the relatively recent introduction of RF into widespread use in medical devices and the potential for masking of the root cause when it is related to RF wireless communication. Device designers should be encouraged to use problem reports as a starting point when estimating probability of occurrence but not base their estimates only on actual experience data.

p. 12/13 Device performance physical specifications

Current Text

- wireless protocol specification name or designation (e.g., WMTS, IEEE 802.11b)
- restrictions on the number or characteristics of other in-band transmitters

Proposed Text

- wireless protocol specification name or designation (e.g., WMTS, IEEE 802.11b, proprietary protocol name, etc.)
- restrictions on the number, characteristics and/or proximity of other in-band transmitters

Rationale

Proprietary protocols are not infrequently used in medical devices so we recommend the guidance explicitly mention them. And restrictions on the proximity of other co-channelled RF wireless devices, in addition to their number and the characteristics, can be important considerations in insuring the integrity of wireless communications and should be mentioned.

p. 13 Software

Current Text

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.

Proposed Text

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. Enhanced software error handling routines capable of preventing injuries when RF wireless communication fails are extremely powerful risk mitigators.

Rationale

Some EMI conditions can be found to make almost any RF wireless communication technology fail. What happens when the technology fails is critical to protection of patient health. Since most devices which can adversely affect human health also employ software in implementing their RF wireless communications, it is important that this guidance encourage developers to exploit its utility in preventing incidents. Enhanced, even redundant, error handling routines can help prevent serious injuries and deaths when RF communication failures occur and should be present in critical care devices.

p. 13 Environmental requirements

Current Text

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

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

Proposed Text

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

- device temperature and humidity limitations
- operation/performance in high RF radiated fields or magnetic fields

- associated sources of EMD, direct and multi-path (from RF reflective surfaces) or screening by materials which might be expected in specific use environments.

Rationale

An elaboration to existing guidance content to alert readers to possible additional factors to consider depending upon the intended use and environment of use for the device.

p. 15 Risk analysis and control measures

Current Text

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.

Proposed Text

We recommend you identify in the context of the intended purpose of your device and its importance to protecting human health:

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

Rationale

The risk analysis focused on hazards of RF wireless communication should be conducted in the context of the device function and role in health care. A single communication failure for a critical care device can have disastrous consequences while multiple failures in a less critical device may be only an annoyance or simply inconsequential. The guidance on risk management application should point to considering the functional role of the device in health care.

p. 16 Paragraph beginning “For EMC...”

Current Text

We recommend your testing include:

- electrostatic discharge (ESD)
- radiated RF electromagnetic energy
- conducted RF electromagnetic energy

- magnetic fields.

Proposed Text

We recommend your testing include:

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

Rationale

Immunity/susceptibility to RF electromagnetic energy is mentioned in the text of the paragraph but is not explicitly included in the bullet list. It should be.

p. 17 First bullet

Current Text

- wireless communications reliability in relation to the primary medical device functions and operation with other in-band transmitters

Proposed Text

- wireless communications reliability in relation to the primary medical device functions and operation with other in-band transmitters at specific separation distance

Rationale

Proximity can be an important factor affecting the quality of RF wireless communications. The list of conditions in the guidance for verifying RF wireless communication functionality should mention separation distance to address instances when this is important.

p. 17 1st paragraph

Current Text

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).

Proposed Text

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 B).

Rationale

Editorial comment. Appendix reference in this document seems to be “B” rather than “C.”

p.20 Labeling

Current Text

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
- susceptibilities discovered.

Proposed Text

To help ensure safety and effectiveness of your device, FDA recommends the labeling include:

- recommended separation distances from other devices or EMD sources
- image frequencies, when appropriate
- adjacent channel RF levels, when appropriate
- conformance to existing standards
- how testing was conducted
- susceptibilities discovered.

Rationale

There should be identification, when appropriate, of image frequencies and adjacent channel RF levels within the labeling requirements.

p. 20 Labeling (continued)

Current Text

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.

Proposed Text

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
- signal bandwidth, when appropriate
- 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
- warning that other equipment could interfere with the equipment or system, even if the other equipment complies with CISPR emission requirements.

Rationale

In addition to the RF type and frequency characteristics of the modulation, there should be reference to the signal bandwidth of the transmitted signals when appropriate but there is no need for bandwidth to be specified in the receiving section (except from the viewpoint of protection against adjacent channel transmissions).

p. 21 Purchasing controls

Current Text

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.

Proposed Text

Delete this text.

Rationale

These requirements reflect general Quality System Regulation (QSR) requirements that do not specifically relate to the subject of this guidance, RF wireless technology. In addition, these topics are already well treated in the QSR itself as well as in QSR-related guidance documents. Recommend that these sections be eliminated as superfluous in this particular guidance document.

p. 27 Reference to FCC

Current Text

Federal Communications Institute (FCC)

Proposed Text

Federal Communications Commission (FCC)

Rationale

Editorial.